

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

SECTION 303

RE: COMMENT on 2005 Medicare allowance for Prostate Cancer drugs.

COMMENT: Please consider whether LCA LCDs are still appropriate for these drugs under the new law. The large physician mark-up was a key driver that created the LCA LCDs. This motivation disappears under the new law. If the relevant ASPs are close, the hassle factor to maintain an LCA LCD may no longer be worth the savings.

The combination of LCA and ACP+6% may drive new behavior:

1. The higher priced products may cost more than the LCA-LCD reduced Medicare allowable. This could cause practitioners to lose money by prescribing their drug of choice, depending on the response of the drug companies (e.g rebates and discounts in a particular quarter.)
2. The lowest cost product may vary quarter to quarter, motivating frequent prescribing changes, depending on the response of the drug companies.
3. Patients may have to change doctors or provider type (e.g. to hospital outpatient) to one willing to lose money on their product of choice, again, depending on the response of the drug companies.
4. Some carriers may not consider the dosing schedules of comparative products to determine allowance calculations, (e.g. once a month vs. once every 28 days--12 vs. 13 units per annum) creating unintended winners and losers;
5. More physicians and beneficiaries may document to the carrier that the higher priced product is reasonable and necessary, and request that the carrier not apply the LCA price reduction for that dose;
6. More beneficiaries may want to continue with the product that has worked for them, and may agree to pay the difference between the ASP+6% of the product of choice and ASP+6% of the lowest cost product (ABN required). This payment would be in addition to the 20% co-pay requirement.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Hemophilia Association of the Capital Area  
3251 Old Lee Highway, Suite 3  
Fairfax, Virginia 22030-1504  
Tel: 703-352-7641

September 23, 2004

The Honorable Mark B. McClellan, M.D. Ph.D., Administrator  
Centers for Medicare and Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
Washington, D.C. 20201

RE: Effect of CMS-1429-P on availability of anti-hemophilia clotting factor

Dear Dr. McClellan:

The Hemophilia Association of the Capital Area (HACA) is a not-for-profit organization established in 1964 that seeks to improve the quality of life for persons with bleeding disorders and their families within the Washington, D.C. region. HACA appreciates this opportunity to comment on CMS's proposed revisions to Medicare payment policies under the physician fee schedule for 2005.

Under the proposed rule, CMS would change how it pays hemophilia treatment centers (HTC) and homecare companies (HCC) that provide blood clotting factor to Medicare patients. CMS would base its 2005 payment rates on manufacturers' average sales price (ASP). This change would translate into a 29% cut in payment rates (from 2004 levels) for recombinant Factor VIII clotting factor products. The proposed rule would also allow a separate \$.05 per unit fee to compensate providers for items and services related to the provision of clotting factor.

HACA and the bleeding disorders community as a whole are painfully aware of the high costs of hemophilia therapies. Hemophilia care can easily cost more than \$100,000 per year, per patient, due to the staggeringly high cost of clotting factor. HACA emphatically has no stake in keeping these costs high; the cost of hemophilia care is a consuming, ongoing problem for all in our community.

But HACA also strongly believes that Medicare beneficiaries (and all other hemophilia patients) must have ready access to appropriate medical care for their bleeding disorders. This access cannot be assured unless health care providers receive adequate payment for hemophilia products. HACA is concerned that a payment rate cut of 29% may be so large that healthcare providers would curtail services to their Medicare patients with hemophilia, undermining medical care for these patients.

HACA is also concerned that the proposed \$.05/unit 'add-on' may be insufficient to pay for the additional services and supplies that are a necessary part of hemophilia care. We recognize that at the time the United States General Accounting Office (GAO) wrote its January 2003 report, it did not have sufficient information from the entire provider community to determine the appropriate level of the costs of providing ancillary services and supplies. We urge you to make every effort to obtain your information from a wide spectrum of the provider community before determining the 'add-on'. However, GAO did recognize that Medicaid's payment should cover the costs of:

1. specialized storage and shipping (factor is a fragile biological product that requires refrigeration);
2. specialized inventory management (as a biological product, factor cannot always be produced in standard concentrations, and may have relatively short expiration dates; these must be carefully matched against individuals' prescriptions);
3. provision of ancillary supplies, such as needles, syringes, tourniquets, and sharps containers; and
4. 24-hour pharmacy staffing, to accommodate patient emergencies.

**CMS-1429-P-3501**

As CMS (and GAO) have recognized, these are critical services and items, necessary for the provision of medical care by HTC and HCCs. The payment for these services and items must be high enough to ensure their continued provision.

We recognize that CMS faces a difficult task. HACA asks only that CMS, in changing the Medicare payment rates for blood clotting factor, place its highest priority on protecting the quality of care for individuals with bleeding disorders. Thank you.

Sincerely,  
Susan A. Yamamoto  
President

CMS-1429-P-3501-Attach-1.doc



# Hemophilia Association of the Capital Area

3251 Old Lee Highway, Suite 3  
Fairfax, Virginia 22030-1504  
Tel: 703-352-7641  
Fax: 703-352-2145  
Web: [www.hacacares.org](http://www.hacacares.org)  
Email: [hacacares@aol.com](mailto:hacacares@aol.com)

September 23, 2004

The Honorable Mark B. McClellan, M.D. Ph.D., Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

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HACA and the bleeding disorders community as a whole are painfully aware of the high costs of hemophilia therapies. Hemophilia care can easily cost more than \$100,000 per year, per patient, due to the staggeringly high cost of clotting factor. HACA emphatically has **no** stake in keeping these costs high: the cost of hemophilia care is a consuming, ongoing problem for all in our community.

But HACA also strongly believes that Medicare beneficiaries (and all other hemophilia patients) must have ready access to appropriate medical care for their bleeding disorders.<sup>3</sup> This access cannot be assured unless health care providers receive adequate payment for hemophilia

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<sup>1</sup> 69 Fed. Reg. 47488 (Aug. 5, 2004).

<sup>2</sup> See 69 Fed. Reg. at 47566 (payment for recombinant Factor VIII products would decrease from \$1.29 per unit to \$.92 per unit in 2005).

<sup>3</sup> GAO reports that approximately 1,100 persons with hemophilia are Medicare beneficiaries. See GAO Report, Medicare: Payment for Blood Clotting Factor Exceeds Providers' Acquisition Cost (GAO-03-184, January 2003) at 6.

products. HACA is concerned that a payment rate cut of 29% may be so large that healthcare providers would curtail services to their Medicare patients with hemophilia, undermining medical care for these patients.

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- specialized inventory management (as a biological product, factor cannot always be produced in standard concentrations, and may have relatively short expiration dates: these must be carefully matched against individuals’ prescriptions);
- provision of ancillary supplies, such as needles, syringes, tourniquets, and “sharps” containers; and
- 24-hour pharmacy staffing, to accommodate patient emergencies.<sup>4</sup>

As CMS (and GAO) have recognized, these are critical services and items, necessary for the provision of medical care by HTC’s and HCC’s. The payment for these services and items must be high enough to ensure their continued provision.

Thank you for considering these comments. We recognize that CMS faces a difficult task. HACA asks only that CMS, in changing the Medicare payment rates for blood clotting factor, place its highest priority on protecting the quality of care for individuals with bleeding disorders.

Sincerely,

*Susan A. Yamamoto*

Susan A. Yamamoto  
President

---

<sup>4</sup> See *id.* at 8, 11-12.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

September 23, 2004

Centers for Medicare & Medicaid Services  
Dept. of Health & Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Subject: Cuts in Cancer Care Reimbursement

Dear Sir/Madame:

This is a comment letter on the upcoming changes in cancer care reimbursement. We are very concerned about the negative impact on our ability to deliver quality cancer care to Medicare patients if the planned reimbursement changes take effect January 1, 2005. Significant cuts in drug reimbursement have been made this year, but we have been able to adequately absorb those cuts due to significant increases in the drug administration reimbursement schedule. In 2005 those increases will be taken away, thus significantly decreasing the overall reimbursement for community-based outpatient cancer care. With the high overhead and fixed costs of running an outpatient cancer center, we have calculated using tools from ASCO and COA that we will have insufficient margin to continue our present style of practicing oncology. At the very least we will be forced to demand the 20% co-pay from Medicare patients prior to their treatment. Most of them cannot afford to pay it, and those who cannot pay will automatically be sent to the hospital for treatment. This ultimately will be much more expensive for the government and the patients. It will also add stress to these patients who already are dealing with a large amount of stress from their diseases. The increased burden to the hospitals will also be very difficult absorb, since many hospitals are already losing money from having to pay for chemotherapy drugs. We agree that changes need to be made to the system, but we think the ASP + 6% system is flawed, especially in the absence of adequate increases in drug administration reimbursement. We cannot operate with negative or intolerably tight financial margins. Further time is needed to study the new system and make necessary refinements after its impact is better understood. Allowing the system to break and then trying to repair it is not the right approach. It will disrupt cancer care for seniors. There will be many very unhappy constituents asking for an explanation from the government how they allowed the system to crash in spite of numerous clear and concise warnings from the oncology community. Please enact an interim system similar to the one in place for 2004 until a more rational new system can be developed and studied. If you have any questions, please do not hesitate to contact us.

Sincerely yours,

David S. Nix, M.D.    John C. Clay, M.D.    John C. Halbrook, M.D.    Dwight S. Keady, Jr. M.D.  
Medical Oncologists

cc: Congressman Chip Pickering; Senator Thad Cochran; Senator Trent Lott

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 10-19**

THERAPY ASSISTANTS IN PRIVATE PRACTICE

I strongly support the proposal to move from a definition of personal supervision to direct supervision. Physical Therapy Assistants have undergone the training and education to provide appropriate therapy services to patients under the supervision of a licensed Physical Therapist.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

COALITION OF RESPIRATORY CARE MANUFACTURERS  
COALITION OF SEATING & POSITIONING MANUFACTURERS  
COALITION OF ENTERAL NUTRITION MANUFACTURERS  
COALITION OF WOUND CARE MANUFACTURERS  
5225 POOKS HILL ROAD SUITE 1626 NORTH  
BETHESDA, MARYLAND 20814

TELEPHONE: (301) 530-7846  
FAX: (301) 530-7946  
E-MAIL: marcia@nusgartconsulting.com

September 23, 2004

Mark McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8012  
Baltimore, MD 21244-8012

Attn: CMS-1429-P ? Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Federal Register 47488 (August 5, 2004) Section 302

Dear Dr. McClellan:

Four distinct coalitions of medical device companies who manufacture durable medical equipment orthotic and prosthetic supplies, The Coalition of Respiratory Care Manufacturers, the Coalition of Seating and Positioning Manufacturers, the Coalition of Enteral Nutrition Manufacturers and the Coalition of Wound Care Manufacturers (hereby known in the rest of these comments as ?The Coalitions?) are pleased to submit these comments in response to Section 302 of the proposed final rule for the Physician Fee Schedule Update for Calendar Year 2005. The Coalitions are comprised of the leading medical device manufacturers of innovative respiratory, seating and positioning, enteral nutrition and wound care products.

The Medicare Modernization and Prescription Drug Act of 2003 (?MMA?) requires the Secretary of Health and Human Services (?HHS?) to establish types or classes of Durable Medical Equipment (?DME?) that require not only a prescription but also a face-to-face evaluation by a physician or other prescribing practitioner. The MMA specifically required this type of evaluation for patients receiving power wheelchairs, based on Congressional concerns about overuse and/or misuse of this specific type of product. In addition, Congress directed CMS to establish clinical criteria for coverage of other types of DME, as appropriate. We believe that Congress intended for CMS to add the new coverage criteria and evaluation requirements when and if there was evidence that these requirements were needed to ensure appropriate utilization of a specific type of product.

However, in Section 302, Clinical Conditions for Coverage of Durable Medical Equipment (DME), CMS now proposes to expand the requirements for clinical conditions for coverage and face-to-face evaluations to all items of durable medical equipment, prosthetics, orthotics and supplies (?DMEPOS?) defined in 42 CFR 410.36. We would like to comment on two of the proposed clinical conditions:

1. Establishing a requirement for a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to determine the medical necessity of all DMEPOS items;

2. Provide that we would promulgate through the national coverage determination process or through the local coverage determination process additional clinical conditions for items of DMEPOS.

1. Establishing a requirement for a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to determine the medical necessity of all DMEPOS items;

In regards to the first two proposed clinical conditions, CMS states the reason for requiring it is because the Agency believes that DMEPOS items should be ordered in the context of routine medical care. While the Coalitions agree that DMEPOS should be ordered in the context of routine medical care, we submit that the vast majority of DMEPOS are currently ordered in an appropriate medical context and that CMS may not be aware of the practical reality of how some items of DMEPOS may be ordered. For example, many items of DMEPOS are ordered in the hospital for the beneficiary's use at home. In this situation, the item is ordered based on a physician's evaluation of the b

CMS-1429-P-3505-Attach-1.doc

CMS-1429-P-3505-Attach-2.doc

**COALITION OF RESPIRATORY CARE MANUFACTURERS  
COALITION OF SEATING & POSITIONING MANUFACTURERS  
COALITION OF ENTERAL NUTRITION MANUFACTURERS  
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September 23, 2004

Mark McClellan, M.D., Ph.D.  
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Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8012  
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However, in Section 302, *Clinical Conditions for Coverage of Durable Medical Equipment (DME)*, CMS now proposes to expand the requirements for clinical conditions for coverage and

face-to-face evaluations to **all** items of durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”) defined in 42 CFR 410.36. We would like to comment on two of the proposed clinical conditions:

1. Establishing a requirement for a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to determine the medical necessity of all DMEPOS items;
2. Provide that we would promulgate through the national coverage determination process or through the local coverage determination process additional clinical conditions for items of DMEPOS.

**1. Establishing a requirement for a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to determine the medical necessity of all DMEPOS items;**

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Secondly, we are concerned that broad application of the face-to-face evaluation requirement is unnecessary to ensure appropriate utilization and will limit access to these products on a timely basis by immobile wound care patients who cannot be transported easily.

For example, home health agency (“HHA”) nurses often see immobile wound care patients who live in rural areas more frequently than their physicians see them. During these visits, sometimes on a daily basis, HHA nurses document both the overall health status of their patients and the condition of the patients’ wound(s). This information is communicated to prescribing practitioners, who, in collaboration with HHA nurses, make decisions about products to be included in comprehensive wound care plans.

Today, if prescribing practitioners determine, based on documentation provided by HHA nurses, that their patients need additional supplies or equipment, they review the clinical criteria published in the medical policy and write prescriptions for medically necessary products. Either the HHA or another Medicare Part B supplier then supplies these products to the patients.

If CMS requires these same patients to be seen by prescribing practitioners before any wound care products can be added to their care plans, the challenge of mobilizing and transporting

patients may cause unnecessary delays in treatment, regression in the condition of treated wounds, and decline in overall health status.

The Coalitions also believe that patients who need wound care, respiratory care or enteral nutrition have face-to-face evaluations by their prescribing practitioners on a regular basis, as may be appropriate for the patients' conditions and the types of products being used to treat their conditions. However, these patients should not be required to have a face-to-face visit in order to have access to the items of DMEPOS necessary to treat their conditions in the home setting when that evaluation is neither necessary nor feasible.

**2. Provide that we would promulgate through the national coverage determination process or through the local coverage determination process additional clinical conditions for items of DMEPOS.**

The companies that comprise the Coalitions frequently collaborate with CMS, Fiscal Intermediaries, Carriers and the Durable Medical Equipment Regional Carriers ("DMERCs") to support the development of National Coverage Decisions ("NCDs") and Local Medical Review Policies ("LMRPs") addressing a wide range of DMEPOS in all care settings. Many of these NCDs and LMRPs already include the kinds of clinical coverage criteria and evaluation requirements that Congress intended CMS to use to ensure appropriate utilization and minimize the risk of abuse and overuse.

For example, the medical policy for continuous positive pressure devices (CPAP) requires that the beneficiary show specific values on a sleep study; the policy for Respiratory Assist Devices (RADs) contains similar criteria and the home oxygen policy specifies blood gas levels measured that will trigger coverage. In these cases, the medical necessity determination is based on the positive results of the diagnostic tests or procedures. Consequently, a further, extensive evaluation by the physician of the sort contemplated in the proposed rule is unnecessary. The clinical support for the DMEPOS should be the test results and the patient's overall condition with which the doctor is already familiar.

CMS acknowledges in the preamble, there already is a process for developing medical coverage policy at the national and local levels. We believe this process works well, especially at the DMERC level because careful consideration is given to applicable criteria for specific items of DMEPOS. Importantly, the process for developing local medical policies includes the opportunity to comment and a requirement that carriers conduct an open meeting to hear public concerns. We strongly encourage CMS to continue to rely on this process to develop clinical conditions of coverage instead of using the rulemaking process it is under taking here. Such an approach will better serve the interests of beneficiaries because it will produce policies that are more closely tailored to the clinical indications for an item of DMEPOS.

**CONCLUSION**

As stated above, most items of DMEPOS already exist local or national coverage policies that have been developed by the DMERC medical directors with extensive input from interested stakeholders, including physician and beneficiary representatives. These policies have been developed after consideration of applicable clinical criteria and may truly be consider “clinical” conditions of coverage. In contrast, the proposed rule is not based on an analysis of the type of DMEPOS and the specific clinical criteria applicable to that item. We note that section 302 of the MMA intends that CMS first establish conditions of coverage for items for which CMS has determined that there has been a “proliferation of use” or for which there have been consistent findings of fraudulent or abusive practices.

We believe that in section 302 of the MMA, CMS should carefully consider the type of DME and what type of standards should be applicable to that item, rather than applying an across the board standard to all covered items. In addition, we urge CMS to remove the requirement for face-to-face evaluation of all items of DMEPOS from the final rule.

We appreciate the opportunity to submit these comments and are available to discuss them with your at your convenience.

Sincerely,

Marcia Nusgart R.Ph.  
Executive Director

**COALITION OF RESPIRATORY CARE MANUFACTURERS  
COALITION OF SEATING & POSITIONING MANUFACTURERS  
COALITION OF ENTERAL NUTRITION MANUFACTURERS  
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September 23, 2004

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The Coalitions also believe that patients who need wound care, respiratory care or enteral nutrition have face-to-face evaluations by their prescribing practitioners on a regular basis, as may be appropriate for the patients' conditions and the types of products being used to treat their conditions. However, these patients should not be required to have a face-to-face visit in order to have access to the items of DMEPOS necessary to treat their conditions in the home setting when that evaluation is neither necessary nor feasible.

## **2. Provide that we would promulgate through the national coverage determination process or through the local coverage determination process additional clinical conditions for items of DMEPOS.**

The companies that comprise the Coalitions frequently collaborate with CMS, Fiscal Intermediaries, Carriers and the Durable Medical Equipment Regional Carriers ("DMERCs") to support the development of National Coverage Decisions ("NCDs") and Local Medical Review Policies ("LMRPs") addressing a wide range of DMEPOS in all care settings. Many of these NCDs and LMRPs already include the kinds of clinical coverage criteria and evaluation requirements that Congress intended CMS to use to ensure appropriate utilization and minimize the risk of abuse and overuse.

For example, the medical policy for continuous positive pressure devices (CPAP) requires that the beneficiary show specific values on a sleep study; the policy for Respiratory Assist Devices (RADs) contains similar criteria and the home oxygen policy specifies blood gas levels measured that will trigger coverage. In these cases, the medical necessity determination is based on the positive results of the diagnostic tests or procedures. Consequently, a further, extensive evaluation by the physician of the sort contemplated in the proposed rule is unnecessary. The clinical support for the DMEPOS should be the test results and the patient's overall condition with which the doctor is already familiar.

CMS acknowledges in the preamble, there already is a process for developing medical coverage policy at the national and local levels. We believe this process works well, especially at the DMERC level because careful consideration is given to applicable criteria for specific items of DMEPOS. Importantly, the process for developing local medical policies includes the opportunity to comment and a requirement that carriers conduct an open meeting to hear public concerns. We strongly encourage CMS to continue to rely on this process to develop clinical conditions of coverage instead of using the rulemaking process it is under taking here. Such an approach will better serve the interests of beneficiaries because it will produce policies that are more closely tailored to the clinical indications for an item of DMEPOS.

## **CONCLUSION**

As stated above, most items of DMEPOS already exist local or national coverage policies that have been developed by the DMERC medical directors with extensive input from interested stakeholders, including physician and beneficiary representatives. These policies have been developed after consideration of applicable clinical criteria and may truly be consider “clinical” conditions of coverage. In contrast, the proposed rule is not based on an analysis of the type of DMEPOS and the specific clinical criteria applicable to that item. We note that section 302 of the MMA intends that CMS first establish conditions of coverage for items for which CMS has determined that there has been a “proliferation of use” or for which there have been consistent findings of fraudulent or abusive practices.

We believe that in section 302 of the MMA, CMS should carefully consider the type of DME and what type of standards should be applicable to that item, rather than applying an across the board standard to all covered items. In addition, we urge CMS to remove the requirement for face-to-face evaluation of all items of DMEPOS from the final rule.

We appreciate the opportunity to submit these comments and are available to discuss them with your at your convenience.

Sincerely,

Marcia Nusgart R.Ph.  
Executive Director

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Massage Therapy can be a powerful tool in helping patients with pain problems. It should not be omitted from the possible therapies available to patients.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THErapy - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments****Issues 20-29**

## THERAPY - INCIDENT TO

I would like to comment of the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar year 2005." In the proposed rule, CMS discusses establishing requirements for individuals who furnish outpatient PT services in physician's offices. CMS proposes that qualifications of individuals providing physical therapy services "incident to" a physician should meet personnel qualifications for physical therapy in 42 CFR 484.4, with the exception of licensure. This means that individuals providing physical therapy services must be graduates of an accredited professional physical therapist program or must meet certain grandfathering clauses or educational requirements for foreign trained physical therapists.

I strongly support CMS's proposed requirement that physical therapists working in physicians offices be graduates of accredited professional physical therapist programs. It is of extreme value and importance to have licensure as a standard - even though current law prevents the agency from requiring licensure, it would be the most appropriate standard to achieve its objective.

Physical therapists and physical therapy assistants under the supervision of physical therapists are the only practitioners who have the education and training to furnish physical therapy services. Unqualified personnel should NOT be providing physical therapy services.

Physical therapists are professionally educated at the college or university level in programs accredited by the Commission on Accreditation of Physical Therapy, an independent agency recognized by the U.S. Department of Education. As of January 2002, the minimum educational requirement to become a physical therapist is a post-baccalaureate degree from an accredited education program. All programs offer at least a master's degree, and the majority will offer the doctor of physical therapy (DPT) by 2005.

Physical therapists must be licensed in the states where they practice. As licensed health care providers in every jurisdiction in which they practice, physical therapists are fully accountable for their professional actions.

Physical therapists receive significant training in anatomy and physiology, have a broad understanding of the body and its functions, and have completed comprehensive patient care experience. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation. This education and training is particularly important when treating Medicare beneficiaries. The delivery of so-called "physical therapy services" by unqualified personnel is harmful to the patient by compromising the patient's own health and well being. Someone unqualified should not be providing treatment or making any clinical decisions or recommendations regarding the patient's health, which could have detrimental effects on the patient.

A financial limitation of the provision of therapy services (referred to as the therapy cap) is scheduled to become effective January 1, 2006. Under the current Medicare policy, a patient could exceed his/her cap on therapy without ever receiving services from a physical therapist. This will negatively impact patient's outcomes by compromising services that the patient could have received, but did not.

Section 1862(a)(20) of the Social Security Act clearly requires that in order for a physician to bill "incident to" for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Thus, the services must be performed by individuals, who are graduates of accredited professional physical therapist education programs.

Thank you for the consideration of my comments.

Sincerely,

Angela Dee

Student Physical Therapist

The College of St. Scholastica

1200 Kenwood Ave.

Duluth, MN 55811

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Therapeutic Massage is becoming widely recognized as a beneficial maintenance to the body as well as aiding in the healing process of many dysfunctions. I feel it would be a great benefit to the people of this nation (Elderly and Diabetes for example, massage improves circulation greatly and helps with Lymphatic drainage) and I would think this nation would be all for improving the peoples options in doing so instead of restricting them. Please do not restrict us as other practitioners from helping the people of this great nation, too.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached

Indiana University  
Department of Sports Medicine  
1001 E. 17<sup>th</sup> Street  
Bloomington, IN 47408-1590

September 20, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy – Incident To

To Whom It May Concern:

We are writing to express my concern over the recent proposal that would limit providers of “incident to” services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- Athletic trainers are highly educated. All certified athletic trainers must have at a minimum a bachelor’s degree from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, injury management and therapeutic exercise, statistics and research design, and exercise physiology. Seventy (70) per cent of all athletic trainers have a master’s degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists,

registered nurses, speech therapists, and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT).

- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Finally as an Educator in an Institution which has both Undergraduate and Graduate Degrees in Athletic Training I am very concerned about the future of my students. These are extremely bright, intelligent, dedicated and motivated young people who have proven themselves already to be worthy supporters of quality health care and I am concerned they will be “shut out” of employment for which they are highly qualified.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Katie Grove, Ph. D., LAT, ATC  
Undergraduate Athletic Training Program Director  
Indiana University Department of Sports Medicine

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

I strongly oppose CMS-1429-P. As the Director of an accredited athletic training education program, I am aware of the preparation and knowledge that Certified Athletic Trainers possess. I have also experienced first hand the high level of professional care they provide to physically active individuals. This is evidenced by the tremendous outcomes seen in the patients they assess and treat. I encourage everyone to examine the professional preparation, certification process and continuing education requirements of certified athletic trainers so an educated decision can be made regarding such an important issue.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

GPCI

The situation in Santa Cruz County, California is in crisis because the GPCI locality assignment (99) is way off base! Santa Cruz exceeds the 5% threshold (105% rule) over the national 1.00 average! I believe Santa Cruz was placed in the wrong Locality (99) and should be reassigned to something which more accurately reflects actual practice expenses. If Santa Cruz County were broken out of Locality 99, it would reflect 112.5%, well above the 105% rule. Doctors leave the county, refuse to take Medicare or severely limit the number of Medicare patients they allow in their practices because reimbursement is so far below their costs. Santa Clara, a neighboring county, is in Locality 9, and doctors receive 25.1% more than doctors in Santa Cruz. Santa Cruz is an expensive county in which to do business. Please help me, as a soon to be Medicare recipient, to receive the medical care I need in my own county.

PLEASE MODIFY COUNTIES, ESPECIALLY SANTA CRUZ COUNTY, WHICH IS 12.5% ABOVE THE NATIONAL AVERAGE, TO REFLECT THE TRUE COSTS FOR MEDICAL PRACTICE.  
Thank you.

Submitter : Date & Time: Organization : Category : **Issue Areas/Comments****Issues 1-9**

SECTION 303

September 20, 2004

Dr. Mark McClellan  
 Administrator  
 Centers for Medicare and Medicaid Services  
 200 Independence Avenue, S.W., Room 341H  
 Washington, DC 20201

Dear Dr. McClellan:

I would like to comment on CMS's proposed payment schedule for drugs and drug administration recently published in the Federal Register. The proposal not only includes a decrease of \$500 million for drug reimbursement in 2005 but also includes a \$150 million decrease for drug administration which only this year was increased to compensate for the 2004 decrease in drug reimbursement. These decreases in funding for cancer care will undoubtedly decrease access to care for our senior citizens. Cancer clinics cannot provide care at a loss and these decreases in reimbursement will force providers to re-evaluate their ability to provide quality outpatient cancer care to our senior citizens. We have estimated that based on reimbursement for the partial list of drugs published by Medicare to date that our practice will see a decrease in revenue of at least 16.7%. Because there will not be a decrease in our fixed costs this percentage decrease is amplified significantly. We estimate that the decrease in our operating capital will be 40% to 50%. We are therefore considering closing some of our rural clinics in Denison, Iowa and Shenandoah, Iowa, which would certainly make access for patients in those rural communities more difficult.

The ASP system that was mandated by the Medicare Modernization Act (MMA) is a flawed system. The ASP price is available only to large drug wholesalers. Community cancer clinics will purchase many drugs at prices above ASP and in some cases above ASP +6%. The fact that there is a reporting time lag of 3-6 months for CMS to publish updated reimbursement rates will also effectively increase our acquisition costs because pharmaceutical companies can raise their purchase price after CMS has determined the reimbursement rate. Our figures show that our direct drug costs including storage, breakage, billing and inventory are at least 12% over drug acquisition cost. ASP + 6% therefore does not come close to covering our total costs. It seems to me that we are replacing one system, the AWP system, which was bad because it was arbitrary with another system, the ASP system, which is bad because it is inaccurate.

CMS has suggested that new billing codes could be created to address under reimbursement for drug administration services. These new codes will only help us recover a small percentage of the decrease in drug administration reimbursement that is scheduled to begin in 2005. If an increase in reimbursement for drug administration was felt to be appropriate this year, I do not understand the rationale for phasing these increases out over the next two years when our expenses for administering these drugs will only continue to increase.

The MMA required three different studies on the effect of these changes on cancer care. I would recommend that instead of rushing into a flawed reimbursement plan which has not been studied and which will undoubtedly have profound consequences on cancer care for elderly patients that reimbursement be frozen at 2004 levels for 2005 or until these studies looking at the effect of ASP on cancer care can be analyzed and remedies can be implemented where problems are discovered. I would recommend that the current system and the proposed ASP system be run in parallel for the next two years and studied.

Dr. Mark McClellan  
 September 20, 2004  
 Page 2

I hope that CMS is committed to maintaining beneficiary access to quality cancer treatment. By making it financially impossible to administer some chemotherapy drugs this year, our cancer drug armamentarium has already been comprised and will be much more comprised next year unless changes in the reimbursement proposal are made.

Joseph Verdirame, M.D.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereas a Physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physician prescription or under their supervision.  
Removing a physician right to prescript the most beneficial therapy to their patients is ethically and morally wrong for the patient.  
The profession of physical therapy is Reactionary Therapy only whereas massage therapy is both reactionary and pro-active; being more proactive and therapeutic.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I feel it short sighted to limit theapy in a doctor's office to only PT services. I feel other therapies, such as massage therapy, would provide the physician with additional options for the complete care of the clients. Please reconsider this disition. Thanks You

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

GPCI

The situation in Santa Cruz County, California is in crisis because the GPCI locality assignment (99) is way off base! Santa Cruz exceeds the 5% threshold (105% rule) over the national 1.00 average! I believe Santa Cruz was placed in the wrong Locality (99) and should be reassigned. If Santa Cruz County were broken out of Locality 99, it would reflect a 1.125% GAF! Doctors leave the county and refuse to take Medicare because reimbursement is so far below their costs. I work for a person who has had several doctors opt out of the Medicare system and she has not been able to receive some services in this county any more. This is wrong. Please help remove the injustices so doctors in Santa Cruz won't need to opt out any more. One day soon I also will want to receive the medical care I need in my own county. PLEASE MODIFY COUNTIES, ESPECIALLY SANTA CRUZ COUNTY, WHICH EXCEED THE 5% NATIONAL AVERAGE TO REFLECT THE TRUE COSTS FOR MEDICAL PRACTICE. Thank you.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

SECTION 303

September 23, 2004

Dr. Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, S.W., Room 341H  
Washington, DC 20201

Dear Dr. McClellan:

I am writing this letter to express my concern about the proposed CMS payment schedule for drugs and drug administration that would directly effect reimbursement for the community cancer clinics. I am part of a single specialty, a hematology/oncology group, and we have several rural clinics in the State of Iowa, as well as in the State of Nebraska. With the CMS new drug reimbursement system based on average selling price (ASP) we estimate that our practice will see a decrease in revenue of anywhere between 15-20%. This percentage decrease is actually compounded by the fact that our fixed cost will not be decreased, and therefore we estimate that the decrease in our operating capital would be 40-50%. This would make it very difficult for us to continue to provide this rural oncologic care, and unfortunately many of our patients in the rural clinics are senior citizens who depend upon our travel to these clinics. I am also afraid that there will not be a good alternative solution for these elderly people and they may not have continued access for proper oncologic care. Eventually this might also be true for patients in our other clinics.

It appears that the crux of the problem is the ASP system because the ASP is available only to large drug wholesalers. Smaller community cancer clinics like ours will have to purchase many drugs at prices much above the ASP level. There is a reporting time lag of three to six months for CMS to publish the updated reimbursement rates, and in essence pharmaceutical companies can raise their purchase price of drugs after CMS has determined the reimbursement rate. In addition, as evident by estimates made in our clinics, our direct drug cost, which would account for storage, breakage, chemotherapy and drug wastage and disposal, billing as well as inventory, would be at least 12% over drug acquisition cost. Therefore ASP + 6% will not cover our total drug cost.

Another issue of concern is the transitional increase for Medicare reimbursement for drug administration that was 32% in 2004 is now scheduled to decrease to 3% in 2005. Unfortunately even in the year 2004, the compensation for the drug administration is estimated to be not even close to cover the proposed decrease in reimbursement over drug acquisition cost. Therefore to further decrease the drug administration to 3% in 2005 would compound the situation.

Dr. Mark McClellan  
September 23, 2004  
Page 2

I think the best course of action for CMS is to hold off on making the proposed changes with regard to average selling price until studies are undertaken that would provide important information about the effect of ASP on the community based cancer clinics. The data obtained from these studies could be analyzed and an appropriate new system could be implemented. I hope you will reconsider the proposed ASP system and maintain the reimbursement for drug and drug administration under the current system until further studies could be performed and the data analyzed.

Sincerely,

Inaganti M. Shah, M.D.

IMS/jas

cc: Representative Steve King  
Senator Chuck Grassley  
Senator Tom Harkin  
Senator Chuck Hagel  
Senator Ben Nelson  
Representative Lee Terry



Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Do not restrict doctors from referring appropriate patients to Massage therapy for treatment of injury, or restrict medicare coverage for such services in appropriate settings with qualified massage therapists. Massage and other body therapy modalities have benefits that lie outside the relm of what patients can recieve from Physical Therapy. Both forms of treatment are vital to a person resolving an injury.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

SECTION 303

September 21, 2004

Dr. Mark McClellan  
 Administrator  
 Centers for Medicare and Medicaid Services  
 200 Independence Avenue, S.W., Room 341H  
 Washington, DC 20201

Dear Dr. McClellan:

In less than four months, the center for Medicare and Medicaid services (CMS) is scheduled to implement a new way that Medicare reimburses community cancer clinics, where over 80% of Americans fighting cancer are treated. The proposal not only includes a decrease of \$500 million for drug reimbursement in 2005, but also includes a \$150 million decrease for drug administration which only this year was increased to compensate for the 2004 decrease in drug reimbursement. These decreases in funding for cancer care will undoubtedly decrease access to care for our senior citizens. Cancer clinics cannot provide care at a loss, and these decreases in reimbursement will force providers to re-evaluate their ability to provide quality outpatient cancer care to our senior citizens. It is estimated that our practice will see a decrease in revenue of at least 16.7% based on reimbursement from the partial list of drugs published by Medicare to date. Because there will not be a decrease in our fixed costs, this percentage decrease is amplified significantly. We estimate that our operating capital will see a decrease of 40-50%. We are therefore considering closing some of our rural clinics in Denison, Iowa and Shenandoah, Iowa, which would certainly make access for patients in those rural communities more difficult.

The new drug reimbursement system is based on average selling price (ASP) reported by pharmaceutical manufacturers to large wholesalers, middlemen between drug manufacturers and cancer clinics, not community cancer clinics. Accordingly, ASP is not a market price available directly to cancer clinics. Cancer clinics report that for many cancer drugs the reimbursement for Medicare will be below their actual cost. There appear to be other problems with this ASP system, including a lack of timely updating of Medicare reimbursement rates to reflect drug price increases, unstable reimbursement rates, and "negative" reimbursement rates (implying that a cancer clinic would have to pay Medicare rather than getting reimbursed). Also, I understand that CMS is working on new Medicare billing codes for drug administration, but no changes have been announced to date.

Our figures show that our drug costs including storage, breakage, billing and inventory are at least 12% over drug acquisition cost. ASP + 6% therefore does not come close to covering our total cost. It seems to me that we are replacing one system, the AWP system, which was bad because it was arbitrary, with another system, the ASP system, which is bad because it is inaccurate. I underscore that my overriding concern is the continued access of all Americans for quality, affordable, accessible cancer care. In this vein, community cancer clinics should be fairly compensated, at competitive market rates, for the drugs and services they provide.

Dr. Mark McClellan  
 September 21, 2004  
 Page 2

I would recommend that instead of rushing into a flawed reimbursement plan, which has not been studied and which will undoubtedly have

profound consequences on cancer care for elderly patients, that reimbursement be frozen at 2004 levels for 2005 or until studies, required by MMA looking at the effect of ASP on cancer care, are available, analyzed and consequently remedies implemented where problems are discovered.

Sincerely,

Samer I. Renno, M.D.

SIR/jas

cc: Representative Steve King  
Senator Chuck Grassley  
Senator Tom Harkin  
Senator Chuck Hagel  
Senator Ben Nelson  
Representative Lee Terry

Submitter :  Date & Time:

Organization :

Category :

Issue Areas/Comments

**GENERAL**

GENERAL

Via Electronic Mail -- <http://www.cms.hhs.gov/regulations/ecomments>

Michael Carter, LAT  
2405 Northwestern Ave.  
Racine, WI 53404

September 15, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of “incident to” services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- Athletic trainers are highly educated. All certified or licensed athletic trainers must have a bachelor’s or master’s degree from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master’s degree or higher. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint the Review Committee on educational programs in Athletic Training (JRC-AT).
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers accompanied the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes

injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Michael Carter, LAT

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

As a massage therapist who has seen speedier recovery for patients/clients who receive massage I can hardly believe you would want to remove this care. There are many who would take advantage of the benefits of massage if there was wider acceptance.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

September 23, 2004

Kevin M. Addison  
255 Hask Jacobs Road  
Blythewood, SC 29016

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy ? Incident To

Dear Sir/Madam:

As a potential Certified Athletic Trainer (ATC) and possible future patient, I feel obliged to write this letter in opposition of proposal CMS-1429-P. I am alarmed that this proposal would limit patient access to qualified health care providers of ?incident to? services, such as ATCs, in physician offices and clinics; thereby, reducing the quality of health care for physically active patients. Furthermore, limiting access to qualified health care providers will cause delays in the delivery of health care, which in turn will increase health care costs and tax an already heavily burdened health care system.

Athletic training is the health care profession that specializes in the prevention, assessment, treatment and rehabilitation of injuries to athletes and others who are engaged in everyday physical activities. Athletic trainers are multi-skilled health care professionals who can, and are, making significant contributions to health care. Athletic trainers are highly educated and fully qualified health care providers, evident in their recognition by the American Medical Association as an allied health care profession. If this proposal would pass, it would threaten the employment of many athletic trainers who are employed as physician extenders in clinics and physician offices. Therefore this proposal threatens my future employment in those settings and the value of my degree in Athletic Training. With this type of limitation artificially placed on the provision of ?incident to? services by qualified (through accredited academic programs in athletic training, a national board examination, and state practice acts) health care providers the CMS will only add to the skyrocketing health care costs, put qualified people out of work, and reduce the overall quality of health care in the United States.

In conclusion, I believe that the CMS-1429-P proposal must be rejected in order to protect the rights (the right to choose and the right for quality care) of our patients and my right as a future health care practitioner.

Sincerely,

Athletic Training Student at University of South Carolina, Columbia

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

On behalf of the one thousand LPTA members in Louisiana, I would like to comment on the CMS proposed personal standards for Medicare ?Incident To Physical Therapy Services?.

I would welcome this new standard. In Louisiana the public is confused. The healthcare consumer does think they are receiving physical therapy from a qualified or licensed physical therapist when administered in the physician?s office. They are only confused when it is pointed out later in a physical therapy clinic that the treatment previously received in the physician?s office was not physical therapy provided by a licensed physical therapist, it was treatment provided by a technician in the physician?s office. Also, patients will wonder why they are progressing so fast with treatment in the physical therapy clinic when it took so long while receiving their care in the physician?s office. Not only was the patient or healthcare consumer confused but there were increased cost to CMS. This change would also assist CMS in tracking true cost for rehabilitation administered by a physical therapist, as we all strive to provide the highest quality of care, at the lowest cost, producing the quickest results. For these reasons, on behalf of LPTA, I support the proposed personal standards for Medicare ?Incident To Physical Therapy Services?.

Our membership also strongly supports the proposed change dealing with PTA supervision from physical therapist to provide ?direct? supervision not the ?in room? supervision.

This change will not diminish the quality of physical therapy services. In Louisiana, the ?in room? requirement is more stringent than the law requires, so we definitely support the ?direct? supervision change.

Thank you for your continued work to make the delivery of physical therapy more professional, more qualified, more cost effective and more respected in today?s healthcare arena.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached file

September 21, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy – Incident To Athletic Training Profession

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of “incident to” services in physician offices and clinics. This proposal should not be adopted because qualified health care professionals would no longer be able to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

1. “Incident to” has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
2. There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY “incident to” service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. ***It is imperative that physicians continue to make decisions in the best interests of the patients.***
3. In many cases, the change to “incident to” services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
4. This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer

- delays in health care, greater cost and a lack of local and immediate treatment.
5. Athletic trainers are highly educated. ALL certified or licensed athletic trainers **must have a bachelor's or master's degree** from an accredited college or university. Foundation courses include: human physiology, human anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy (70) percent of all athletic trainers have a master's degree or higher. This great majority of practitioners who hold advanced degrees is comparable to other health care professionals, including physical therapists, occupational therapists, registered nurses, speech therapists and many other mid-level health care practitioners. Academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT).
  6. To allow *only* physical therapists, occupational therapists, and speech and language pathologists to provide "incident to" outpatient therapy services would improperly provide these groups exclusive rights to Medicare reimbursement. To mandate that only these practitioners may provide "incident to" outpatient therapy in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
  7. CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
  8. CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. ***In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.***
  9. Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to **prevent, assess, treat and rehabilitate** injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of walking in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
  10. As a graduate student of kinesiology and athletic training at the University of Kentucky I am in the College of Health Sciences in an Academic Medical Center. My colleagues and I are disappointed that CMS has taken such a myopic view of allied health professionals. I am confident and have data to support that students in the allied health profession are experts in treatment and rehabilitation of the

physically active. I am confident that your exclusion of athletic trainers as currently written in the proposal was an oversight. I am sure our legislative representative in Kentucky, particularly, Senator Jim Bunning would disagree with your stance. Senator Bunning was a professional athlete who was privy to the advantages and academic preparation and skills of a certified athletic trainer.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

Rebecca I McClelland, ATC, CSCSGraduate Assistant Athletic TrainerUniversity of  
KentuckyEJ Nutter Training Facility  
136 Sports Center Drive  
Lexington KY 40506-----\*Office: (859) 257-6521\*Fax:  
(859) 257-8953\*E-Mail: beckymcc@uky.edu

Submitter : Mrs. Tina Shockley Date & Time: 09/23/2004 09:09:17

Organization : Progressive Physical Therapy

Category : Physical Therapist

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

September 23, 2004

Dear Sir or Madam:

I support the revised "Incident To" requirements proposed by the 2005 CMS fee schedule in which only individuals meeting the existing qualifications and training standards will qualify to provide therapy services incident to physicians' services. This change in CMS policy will provide quality care to Medicare recipients in this country.

I am a physical therapist and clinical director practicing for seven years in the Los Angeles area. On a very consistent basis I receive new patients who have been treated in physician offices and were unhappy with their care. Reasons for their dissatisfaction vary, but here are a few:  
?? I was not comfortable having a non-licensed individual treat me for my sequestered disc. They couldn't even explain what it was that I had.  
?? Nobody was able to explain to me how ultrasound works or what its purpose was.  
?? My program never progressed. I found out later that the individual treating me was brand new and had no knowledge of my diagnosis, my pain, my rehabilitation process, etc.?

After being evaluated and treated by a therapist, they couldn't believe 1) their own understanding of what was going on with their body from the education they received about their diagnosis, 2) their decrease in pain secondary to an appropriate plan of care, and 3) the difference in explanation of how and why modalities were used and what to expect from the rehabilitation process.

On several occasions, I have also interviewed individuals who worked at MD offices in the PT department. I cringed when I heard neither a PT nor an MD were on the premises while patients were being treated by PT aides and techs. This is illegal and happening everyday.

The proposed "Incident To" rule will ensure that scenarios such as the ones I have described above will no longer take place. Medicare beneficiaries will receive the rehabilitation therapy from skilled, well trained and educated professionals. To reiterate, I am in strong support for this new policy.

Sincerely,

Tina Shockley, BS, PT, CPI, CSCS

Submitter : Mrs. Jennifer Ashburn Date & Time: 09/23/2004 10:09:53

Organization : AMTA

Category : Other Health Care Professional

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I implore you to NOT pass this policy, whereby a physician can only refer "incident to" services to physical therapists. ALL qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. Please protect massage therapists's rights to work with or for medical doctors or chiropractors.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

September 23, 2004

Dear Sir or Madam:

I would like to express my support for the revised 'Incident To' requirements proposed by the 2005 CMS fee schedule in which only individuals meeting the existing qualifications and training standards will qualify to provide therapy services incident to physicians' services. This change in CMS policy will go a long way toward bringing more common sense to Medicare recipients in this country.

As a practicing physical therapist I have treated numerous patients that have reported to me the poor quality of care frequently provided by untrained individuals in physicians' offices. Yet what is more compelling is the story a young former employee of my clinic shared with me. I must withhold his name because he left our employment to attend full-time college coursework and I haven't been able to reach him for permission to use his name, however his story is not unusual.

This particular young man (I'll call him 'James?') was hired about 1 year ago at the physical therapy clinic in which I work. Prior to working here, he was employed by a physician to provide 'therapy' in that doctor's office. James related to me that he had no prior experience with this type of work, nor did he have any understanding of the rationales or physiologic effects of the various modalities he dispensed. The physician would simply write orders for particular procedures and modalities and James would do the best he could to carry them out. However he admits that he could rarely perform these with any real competence because he lacked the training and skills necessary to do so.

James discovered much of this after he worked in our clinic for several months. While working with professional therapists James gradually began to gain skills that he lacked while working for a physician. He learned that rehabilitation is a science and that physical therapists undergo rigorous training to learn that science. While physicians receive a painstaking medical education, their expertise is not rehabilitation. They certainly cannot provide the same positive patient outcomes with untrained employees that are so common place with skilled, formally trained therapists.

The proposed 'Incident To' rule will ensure that scenarios such as the one I have described to you no longer take place. Medicare beneficiaries will receive the rehabilitation therapy from skilled, well-trained professionals, and this is why I wish to strongly voice my support for this new policy. Thank you for your time.

I would be pleased to discuss this issue with your further at your convenience.

Gary L. Cunningham, MPT

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 10-19**

SECTION 623

Re. Revised ESRD Composite Rates Effective 1/1/05 (p. 47535)

When this proposed rule is finalized and an implementing CR is issued, please specify in the CR that ESRD MSA groupings for composite rates are based on the MSA groupings published in the 8/15/86 Federal Register and not the latest MSA groupings. Also, it would be very helpful if Composite Rate Table 18 published on pp. 47536-47541 showed the counties comprising each MSA.

For example:

- Baltimore, MD
- Anne Arundel, MD
- Baltimore, MD
- Baltimore City, MD
- Carroll, MD
- Harford, MD
- Howard, MD
- Queen Annes, MD

Additionally, MSA # 2030 Decatur AL and #0470 Arecibo PR are both shown as MSAs in table 18, but were not MSAs in the 8/15/86 notice.

Finally, we recommend that any updates to the composite rates also include an update to the latest MSA tables to more truly reflect current conditions. By using the MSA tables published in the 8/15/86 Federal Register, many providers are disadvantaged due to being classified as rural in 1986 when current conditions dictate that they be included in an MSA. For example, Ashtabula County, Ohio is now part of the Cleveland MSA where in 1986 that county was designated as rural.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please do not pass this policy. Every patient should have the right to see a specialist if their physician writes a Rx for it.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Athletic trainers have just as much a right to help people recover from athletic type injuries as a physical therapist. Also, the physician should be the one to advise the patient on what type of care and treatment are best for them, not a government worker.

Submitter : Mrs. Melody Henry Date & Time: 09/23/2004 10:09:09

Organization : Dr. Singh/ Dr. Arora

Category : Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

So Much more is involved in providing chemotherapy to patients other than just the cost of the drug. Nurses in hospitals are not certified on Oncology, which helps them to properly treat cancer patients. As well as the expense alone of being in the hospital overnight, delays in receiving proper chemo treatments have a tremendous effect on the overall patient response to treatment. Outpatient chemo clinics are more reliable, convenient, safe and overall would save money to the government instead of placing patients in hospitals for their treatments. This would force clinics to send pts. to the hospital where it is more costly, and requires much more time. For the sake of cancer patients everywhere please consider this matter carefully-do not make the clinics close.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please save the our right to work with medical doctors or chiropractors as massage therapists and allow our family and friends to receive professional health care in a physicians offices from those other than physical therapists only. Massage therapists in New York State have been discriminated against. We are required to fulfill a degree program and pass a New York State Board Exam, Since 1929! We are the professionals who have expertise with the muscular system and are not covered under the current Medicare Law. Include Licensed Massage Therapists as covered therapists for medically necessary treatment. Thank you for your consideration.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

allow Licensed Massage Therapists to provide services prescribed by chiropractors, naturepaths and Medical Doctors.  
Many of my clients get better results with massage modalities and with just physical therapy.  
thank you  
Diane Perkins

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

As a health care provider, I see benefit in having various providers included in the treatment of patients/clients in various medical clinics in which I have practiced. I oppose limiting the types of professionals who can provide therapy in doctors offices. I would like to include other therapists, such as (but not limited to) craniosacral therapists, massage therapists, acupuncturists, etc. in the delivery of therapy when appropriate in a medical setting. Physical therapists should not be the only professionals allowed to practice and be reimbursed for treatment in a medical setting/in a clinic.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

OTHER - INCIDENT TO

I wish to comment on the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." I want to express strong support for CMS's proposed requirement that physical therapists working in physicians' offices be graduates of accredited professional physical therapist programs. The value of licensure as a standard, even though current law prevents the agency from requiring licensure, it would be the most appropriate standard by which to achieve the objective of this rule.

I am a physical therapist assistant and currently in my final year of my masters degree to become a physical therapist. I work at Miami Valley Hospital in Dayton, OH in the outpatient physical therapy department. I have worked in nearly all areas of physical therapy in some capacity. I started as a volunteer back in 1994 and then became a physical therapy aide in 1997. While working as an aide, I felt that I knew enough to do my job effectively. As I advanced in school, I realized how much I didn't know and that at times I had put patients in danger due to my lack of knowledge. When I graduated in 1999 with my physical therapist assistant degree, I again felt very confident in my abilities to treat patients. I didn't feel there was much difference between me and a physical therapist except the pay difference. Again, as I progressed through the physical therapist program at the University of Findlay, I realized even more so how wrong I was. There is a huge difference between the training of a physical therapist assistant and a physical therapist. I feel very confident in the ability of physical therapist assistants to treat patients, but definitely under the guidance of a physical therapist. I can't imagine leaving the treatment of a patient in the hands of a lesser trained individual. I fully plan on continuing on to get my doctor of physical therapy (DPT) degree, so that I'm prepared to be the first contact as our profession moves into direct access. All programs offer at least a master's degree, and the majority will offer the DPT degree by 2005. Physical therapists must be licensed in the states where they practice. As licensed health care providers in every jurisdiction in which they practice, physical therapists are fully accountable for their professional actions.

A financial limitation on the provision of therapy services is scheduled to become effective January 1, 2006. Under the current Medicare policy, a patient could exceed his/her cap on therapy without ever receiving services from a physical therapist. This will negatively impact patient's outcomes because physical therapists have extensive training in developing individualized therapy programs by which these patients are progressed through. I speak from experience when I say that anyone with lesser training than a physical therapist assistant is inadequate to provide high quality and effective therapy to Medicare patients. Section 1862(a) (20) of the Social Security Act clearly requires that in order for a physician to bill "incident to" for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Thus, the services must be performed by individuals, who are graduates of accredited professional physical therapist education programs.

Thank you for your consideration of my comments.

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

**Subject:** Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

**Reference “Therapy-Incident To”**

I wish to comment on the August 5 proposed rule on “Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.” I want to express strong support for CMS’s proposed requirement that physical therapists working in physicians’ offices be graduates of accredited professional physical therapist programs. The value of licensure as a standard, even though current law prevents the agency from requiring licensure, it would be the most appropriate standard by which to achieve the objective of this rule.

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A financial limitation on the provision of therapy services is scheduled to become effective January 1, 2006. Under the current Medicare policy, a patient could exceed his/her cap on therapy without ever receiving services from a physical therapist. This will negatively impact patient’s outcomes because physical therapists have extensive training in developing individualized therapy programs by which these patients are progressed through. I speak from experience when I say that anyone with lesser training than a physical therapist assistant is inadequate to provide high quality and effective therapy to Medicare patients. Section 1862(a) (20) of the Social Security Act clearly requires that in order for a physician to bill “incident to” for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Thus, the services must be performed by individuals, who are graduates of accredited professional physical therapist education programs.

Thank you for your consideration of my comments.

Duke W Hartwell, PTA

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Courtney Burken  
Box 8010 900 College Street  
Belton, Texas 76502  
September 23, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy ? Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

? A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, it is imperative that physicians continue to make decisions in the best interests of the patients.

? In many cases, the change to ?incident to? services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. Outside referrals will involved delay of care and patient time and travel expense. Delaying recovery will ultimately lead to increased medical expenditures of Medicare.

? To mandate that only a few select practitioners may provide ?incident to? care in physicians? offices would improperly remove the states? right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

? CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services without statutory authority to restrict who can and cannot provide services ?incident to? a physician office visit. In fact, this action may be an attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.

? Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

? Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY STANDARDS AND REQUIREMENTS

I oppose this change requiring physicians to refer patients only to Physical Therapists and not Massage Therapists. I was in an auto accident a couple of years ago and received Chiropractic care, massage therapy and physical therapy as my treatment. I beleive I was able to get better because of the combination of treatment. Not one of these professions alone could have helped as much as the treatment of all 3.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 10-19**

THERAPY ASSISTANTS IN PRIVATE PRACTICE

I support CMS new proposal that PTAs do not need personal, in the room supervision, and that in suite supervision is sufficient. They have the education and training and the professionalism to safely and effectively deliver treatment without having a PT hover over them in the same room.

It is also not fair that in home health and hospitals, they function without in room supervision, when in fact pts are more acute in those situations! Lets have more consistency for our Medicare patients, and give PTAs the respect they deserve.

**Issues 20-29**

THERAPY - INCIDENT TO

I support CMS's proposal to raise the standards of who may deliver Physical Therapy services and bill for this as Physical Therapy. I have been a PT for 30 years and personally know of many offices where MDs delegate PT modalities and exercise to unlicensed personnel and call this physical therapy. Physical Therapists and Physical Therapist Assistants are the only people who have the education and training to safely evaluate what are they appropriate services and to deliver them. We are experts in the musculoskeletal system and many Medicare beneficiaries depend on physical therapy to help them walk and regain their function and lives. Lets give them the best of the best, and protect them from people who are not professionally trained to help. Thank you for your consideration of my comments.

Submitter : Mrs. Melody Henry Date & Time: 09/23/2004 10:09:42

Organization : Dr. Singh/Dr. Arora

Category : Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

Chemotherapy does not just involve the cost of the drug-there is also the cost of other supplies needed such as huber needles, safety catheters, IV bags, tubing, IV pumps, waste containers, dressings,etc.The list goes on and on. This also does not account for patient teaching giving them the time to have explained exactly what is happening to them, side effects etc. Also the different types of chemo treatments are more complicated than they used to be years ago- more time is needed to properly assess patients-make sure chemo is given in proper sequence, IV run time, accessing hepatic pumps for chemo, etc. This list is endless too. Hospitals are not the answer for these patients. Hospitals are more costly -even for a bandaid. The overall cost would be much greater if these patients end up having to have their chemo treatments in hospitals instead of outpatient clinics. Please do not make this mistake a reality.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Massage Therapy is a very important part of health care and a health care complement. This needs to be this recongized as an improtant part of health care.Please do NOT pass this policy whereby a physician can only refer 'incident to ' sevicess to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

It was brought to my attention that there is a proposal issued that will cause amendments regarding your policies on ?Therapy ? Incident to? billing services under the supervision of a physician.

It appears that the amendments will limit the services Certified Athletic Trainers are providing to Medicare recipients.

With earning a Master?s degree and 7 years experience as a Certified Athletic Trainer in Outpatient Physical Therapy settings I am displeased that I may be limited on performing skills that have produced excellent outcomes for your clients and our patients.

It is my hope that you will reconsider making changes to your current policies and allow those Certified Athletic Trainers with proven education, training and outcome success to serve individuals of ALL AGES receiving Medicare.

**Terrie A. Scherer**

215 N. 28<sup>th</sup> Street  
Richmond, VA 23223  
**Terrie.Scherer@att.net**

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P (Pam West)  
P.O. Box 8012  
Baltimore, MD 21244-8012

September 24, 2004

To Whom It May Concern:

It was brought to my attention that there is a proposal issued that will cause amendments regarding your policies on “Therapy – Incident to” billing services under the supervision of a physician.

It appears that the amendments will limit the services Certified Athletic Trainers are providing to Medicare recipients.

With earning a Master’s degree and 7 years experience as a Certified Athletic Trainer in Outpatient Physical Therapy settings I am displeased that I may be limited on performing skills that **have produced excellent outcomes for your clients and our patients.**

It is my hope that you will reconsider making changes to your current policies and allow those Certified Athletic Trainers with proven education, training and outcome success to serve individuals of ALL AGES receiving Medicare.

If there are any other questions please contact me through [Terrie.Scherer@att.net](mailto:Terrie.Scherer@att.net).

Thank you for your time.

Sincerely,  
Terrie Scherer

Submitter : Vera Date & Time: 09/23/2004 10:09:57

Organization : Vera

Category : Individual

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am a first year PTA student. I'm thankful for this opportunity to voice my opinion. As a former patient myself and knowing others who have needed the care of a Physical Therapist I can't imagine having this kind of care ever being delivered by anyone who is not licensed to do so. As a student, my main concern is for the patient. All of us have a right to specialized care.

Sincerely, Vera SPTA

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please do NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. I beleive and I speak as a patient and a practitioner, it should be the dicission of the patients, on what kind of services they think would benefit them. Not everyone can heal by the same type of work, every body is different. Medication as an example, can have different chemical effects from one person to another, it all effect everyone differently. So if you make patients only be able to go to Physical therapists. Some people will heal, and maybe not to the full potential and some will not heal at all. I also beleive this would be going against the all provider statue, all insurance companies have to follow.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dear Dr. McClellan:

I am an associate professor and director at the University of Indianapolis, Krannert School of Physical Therapy. I am in strong support of the August 5 proposed rule on 'Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.' Please refer to the attached document.

Thank you for your consideration of my perspective.  
Sincerely,

Christopher L. Petrosino, PT, PhD  
Associate Professor/Director  
Krannert School of Physical Therapy  
University of Indianapolis  
Indianapolis, IN 46227  
Ph: 317-788-2182 Email: cpetrosino@uindy.edu

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: "Therapy-Incident To"

Dear Dr. McClellan:

I am an associate professor and director at the University of Indianapolis, Krannert School of Physical Therapy. I've been practicing as a physical therapist for 14 years and teaching in undergraduate (i.e., pre-physical therapy prerequisite courses) and graduate (i.e., master's and doctor of physical therapy courses) courses for 9 years. I am writing in strong support for CMS's proposed requirement that physical therapists working in physician offices be graduates of accredited professional physical therapy programs.

As a director of an entry-level doctor of physical therapy program I can attest to the fact that physical therapists and physical therapist assistants under the supervision of physical therapists are the *only* practitioners capable of providing physical therapy services. I encourage you to review the education and training requirements that our students undertake on their way to becoming licensed physical therapist ([http://pt.uindy.edu/dpt/eldpt\\_curriculum\\_outline.htm](http://pt.uindy.edu/dpt/eldpt_curriculum_outline.htm)). Any program that is accredited by the Commission on Accreditation in Physical Therapy Education will have met stringent requirements to hold that accreditation. Is there any wonder why we, as licensed health care providers, fear for our patients and practice when unqualified personnel are claiming to provide "physical therapy services?" Physicians do not have the same scope of practice as physical therapists and should not be supervising unlicensed personnel in the treatment of patients and calling their treatment physical therapy. Nonetheless, most physicians recognize the specialized knowledge base of physical therapists and regularly refer their patients to physical therapists. Those physicians that do provide physical therapy services in their office without licensed physical therapists are going beyond their scope of practice, placing patients at risk of further injury or inadequate physical therapy treatment, and are primarily interested in financial gain more than patient care.

For these reasons I am in strong support of the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." The qualifications of individuals providing physical therapy services "incident to" a physician should meet personnel qualifications for physical therapy services (see 42 CFR 484.4).

Thank you for your consideration of my perspective.  
Sincerely,

Christopher L. Petrosino, PT, PhD  
Associate Professor/Director  
Krannert School of Physical Therapy  
University of Indianapolis  
Indianapolis, IN 46227  
Ph: 317-788-2182 Email: cpetrosino@uindy.edu

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

We object to the proposed policy whereby physicians can refer only "incident to" services to physical therapists. Certified massage therapists, acupuncturists and other qualified health care providers must be allowed to provide services to patients with a physician's prescription or under their supervision for the overall welfare of the patient. Do not take a step backwards when thousands of patients are availing themselves of integrative medicine practitioners. The attending physician must have the freedom to prescribe the protocol that best suits the needs of the patient.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

It is important that you do NOT pass this policy where a physician can only refer "incident to" services to physical therapists. ALL qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached MS Word file entitled CMS letter.doc

Mike Van Veghel LAT, CSCS  
244 Taylor Street  
Cottage Grove WI 53527

9/20/04

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of "incident to" services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients who, in many cases, are extremely active and benefit greatly from the care provided to them at the UW Health Sports Medicine Center. Ultimately, these limitations would increase the costs associated with these services and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician's professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to "incident to" services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working "incident to" the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician's office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient's recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate "incident to" procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide "incident to" care in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers were part of the US Olympic Medical Staff and accompanied the

U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Thank you for the opportunity to express my concerns regarding this very important issue.

Sincerely,

Mike Van Veghel LAT CSCS  
Licensed Athletic Trainer  
UW Health Sports Medicine  
621 Science Drive  
Madison WI 53711

Home Address:  
244 Taylor Street  
Cottage Grove WI 53527

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Ryan C. McMahan, ATC  
 2084 Kinter Ave  
 Hamilton, NJ 08610  
 September 23, 2004  
 Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attention: CMS-1429-P  
 P.O. Box 8012  
 Baltimore, MD 21244-8012  
 Re: Therapy ? Incident To  
 Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of ?incident to? services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

? Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician?s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician?s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient. ? There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.

? In many cases, the change to ?incident to? services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.

? This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working ?incident to? the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

? Patients who would now be referred outside of the physician?s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient?s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

? Curtailing to whom the physician can delegate ?incident to? procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician?s ability to provide the best possible patient care.

? To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide ?incident to? services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide ?incident to? care in physicians? offices would improperly remove the states? right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

? CMS, in proposing this change, offers no evidence that there is a problem that is need

Ryan C. McMahon, ATC  
2084 Kinter Ave  
Hamilton, NJ 08610

September 23, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of “incident to” services in physician clinics. If adopted, this would eliminate the ability of qualified health care professionals to provide these important services. In turn, it would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to “incident to” services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments

- elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
  - Patients who would now be referred outside of the physician’s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient’s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
  - Curtailing to whom the physician can delegate “incident to” procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician’s ability to provide the best possible patient care.
  - To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.
  - CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
  - CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
  - Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
  - Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are

- unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.
  - Physical Therapists state that they are the most qualified professional to provide “incident to” services. How can they say they are qualified professionals when at a local Physical Therapy clinic a majority of the Physical Therapist do not have even a basic CPR certification.
  - Physical Therapist and Assistants are not required to maintain or gain any Continuing Education Units. Certified Athletic Trainers are “required” to obtain a set amount by our Board of Certification every three years clearly showing that our qualifications not only are soundly based, but continually being invigorated and expanded.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care access deterrent.

Sincerely,

*Ryan C. McMahon, ATC*

Ryan C. McMahon, ATC

2084 Kinter Ave  
Hamilton, NJ 08610

Submitter : Mrs. Tambi Osier Date & Time: 09/23/2004 10:09:45

Organization : Judy's Intimate Apparel

Category : Other Health Care Professional

Issue Areas/Comments

**GENERAL**

GENERAL

We were recently made aware of a proposed rule change to Medicare policy that would adversely affect women who wear breast prostheses (L8030), post-mastectomy bras (L8000) and other post-mastectomy items (L8020, L8015, L8035, K0400).

Proposal (CMS-1429-P)

I ask that you exempt breast cancer survivors and the above listed DME codes.

The proposed new rule would require that prior to the purchase of a Medicare covered item, the recipient would have to have visited their physician in person to receive the prescription. The prescription would then have to be filled within 30 days. The rule would require that the face-to-face visit be for the sole purpose of the evaluation or treatment of the medical condition and not for the sole purpose of obtaining a prescription for the DME item, otherwise coverage will be denied.

For a breast cancer survivor this is a ludicrous request. Breasts do not grow back! There is no additional treatment after an amputation and subsequent radiation and chemotherapy. A missing breast cannot be examined, probed, nor subjected to mammography. In addition, breast prostheses have a limited life. They can split, loose their shape or leak. Post-mastectomy bras, just like other textiles, wear out over time. If a woman needs a replacement for normal wear and tear, she should be allowed to request a prescription over the phone and the physician be allowed to fax the prescription to the DME provider.

Further, when a woman is deemed cancer free, she is released by her oncologist from further medical visits for this condition. In the event that a woman needs an emergency replacement of any post-mastectomy product, this rule could preclude her from immediate replacement. It would also adversely affect women who travel or live in nursing home and assisted living facilities.

For breast cancer survivors, this proposed rule will cost Medicare more money with the unnecessary patient visits and waste the valued time of physicians who are overburdened and could be seeing patients with an emergent medical need.

Sincerely,  
Tambi Osier  
Manager & BOC Certified Fitter  
Judy's Intimate Apparel, Inc.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

SECTION 303

see attached electronic file

CMS-1429-P-3555-Attach-1.pdf

September 22, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS 1429-P  
PO Box 8012  
Baltimore, MD 21244-8012

**RE: CMS-1429-P: Section 303**

Sir/Madam:

Please consider these comments to the recently released "Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005" in particular Section 303 in finalizing the proposed rule. These comments relate to rules CMS is seeking to enact pursuant to provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Effective January 1, 2005, there are fundamental changes proposed to reimbursement for drugs furnished incident to a physicians' service under Medicare Part B. The reimbursement will change from one in which these drugs are reimbursed on an average wholesale price (AWP) basis to one based upon the average sale price (ASP).

Under the AWP system, many of the services provided (such as administration costs, nursing care, materials management, billing and reimbursement personnel and patient monitoring) were cross-subsidized by the perceived overpayment for the drug itself. Under the proposed ASP formula, CMS seeks to end the cross-subsidy and instead seeks to provide an increased payment for services. However, the increased reimbursement for services does not take into account all of the services provided and does not come close to making up the difference.

Metechos Management Group, LLC is a physicians' practice management entity that is specifically involved in the provision of infusion services in an office setting to some of Medicare's most ill patients. Based upon our research among our physician clients, using intravenous immune globulin (IVIg) as a model, the switch to the ASP formula is not simply going to cut into a profit margin. Instead, the physicians are going to be left in a position of a net loss on EACH Medicare patient to whom they provide this service.<sup>1</sup> Obviously, under those circumstances, the physicians will simply be unable to provide this service to Medicare patients, thus reducing access, which is one of CMS's critical concerns.<sup>2</sup>

---

<sup>1</sup> We believe that the estimates made earlier this year by CMS suggesting the net effect of the switch from AWP to ASP vastly underestimates the actual affect. Our own internal research suggests a much larger cut in reimbursement more in keeping with that estimated by the American Society of Clinical Oncology (see attached article -- **Medicare cancer drug cuts double estimates Proposed payments inadequate, survey of doctors shows**)

<sup>2</sup> Further, and easily as alarming from the physician standpoint is that many provider agreements with health insurance organizations, PPO's, HMO's have a fee schedule that is tied to the Medicare reimbursement schedule. As such, Medicare's drastic reduction in reimbursement for covered outpatient drugs is not simply going to affect access for Medicare patients. Instead it is going to drastically affect providers ability to provide covered outpatient drugs to patients with private insurance as well.

A likely consequence to Medicare of the retreat of physician office practices from providing these kinds of services to Medicare beneficiaries is that they will instead find themselves receiving services in a hospital outpatient or even inpatient setting. In the hospital outpatient setting Medicare will actually see an increase in the amounts reimbursed based upon the Hospital Outpatient Prospective Payment System. Further, the outpatient departments of most hospital systems are simply not in a position to handle the additional patient load, thus delaying treatment to very sick patients. (*see attached article - Waiting game plagues world-renowned hospital; Financial problems threaten health care at public facilities*) Should the patients end up being admitted to a hospital for inpatient treatment the cost to Medicare will increase even more drastically. Again, as with the outpatient setting, the capacity to handle the influx of patients is simply not available thereby delaying or denying treatment.

We are aware of the comments that CMS has received from various Oncology groups suggesting that the use of ASP is going to cause a number of providers to simply cease providing drugs to Medicare beneficiaries on an outpatient basis. We echo those sentiments. We wish to insure that CMS is aware that cancer treatment is not the only area that is likely to experience such a phenomena. We represent infectious disease doctors, internal medicine doctors and neurologists in seven (7) states that are going to be left with little alternative but to walk away from providing this service.

We would also echo those concerns outlined in the comments of the Community Oncology Alliance related to some of the key problems with ASP. Specifically, we would note that ASP is not going to reflect a market price available to any particular physician practice. CMS cited the availability of group purchasing organizations (GPO) in the proposed regulation as a mechanism around pricing concerns for individual physician practices. However, even in the GPO environment, better prices, terms and discounts are provided based upon the volume of purchase. Therefore, a relatively small physician practice is not going to be able to get the best price available merely by joining a GPO.

Further, many of the available products on the market (which share the same HCPCS code) are going to have an actual price above the ASP. Therefore, as a practical matter, those higher cost products will become unavailable to Medicare beneficiaries as physicians will lose even larger sums by using them.

We also have our concerns regarding CMS' ability to administer such a data intensive unwieldy system. To attempt to crunch the numbers on ALL sales data from ALL drug manufacturers on ALL of the drugs they sell every ninety (90) days to determine ASP seems wrought with the possibility for delay and confusion. It also means that given the six month lag expected in applying ASP, price increases for drugs will not be reflected in reimbursement for an extended period, leaving physicians even further in the hole.

While ASP may make a certain conceptual sense, we do not believe that it is functional in application. As such, we would urge, on behalf of our physician clients, CMS to consider those issues raised herein and by colleagues in oncology. Given the conceptual and unproven experiment represented by the ASP payment system, we believe that CMS should be allowed to conceptually administer the ASP system for 2005 alongside the traditional AWP model. This will allow CMS to determine if the administration of the ASP model is feasible and workable. Further, it will allow physicians (and CMS) to identify the true effects that the ASP model will have on their practice.

In summary, while we understand and applaud Congress and CMS' efforts to obtain fair and balanced Medicare reform, the ASP system as proposed is very likely to have a negative impact on access to the healthcare system and to particular therapies. Much like with cancer treatments, other therapies are going to be relegated to being provided in a hospital outpatient setting which will impose an additional burden on the Medicare system.

Thank you in advance for your consideration.

Sincerely,

*Craig Choate*

Craig A. Choate  
General Counsel

Metechos Management Group, LLC  
1920 N Memorial Way, Suite 200  
Houston, TX 77007  
713-333-7890

On behalf of:

INFECTIOUS DISEASES ASSOCIATES  
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Victor Fainstein, M.D.  
Mary F. Weinert, M.D.  
Dipti Agrawal, M.D.

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Patrick N Harding, M.D.

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INFECTIOUS DISEASES, P.C.

Virginia Wells, M.D.

GEORGE G. BURNAZIAN, M.D., P.A.  
George G Burnazian, M.D.

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James E. Pugh, M.D.  
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T. Drake McDonald, M.D.  
Kenneth T. Ashkin, M.D.  
Robert A. Nahouraii, M.D.  
T. Erik Borresen, M.D.  
Michael M. Amiri, M.D.

THE NEUROLOGY CENTER, P.A.

Julia L Jones, M.D.  
Igor M Cherches, M.D.  
J. Gavin Norris, M.D.  
Steven Lovitt, M.D.

NEUROLOGICAL ASSOCIATES, INC.

John M. O'Bannon, III, M.D.  
John J. Brush, M.D.  
Robert J. Cohen, M.D.  
J. Kim Harris, M.D.  
John D. Blevins, M.D.  
Philip A. Davenport, M.D.  
Susanna A. Mathé, M.D.  
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Stephen E. Thurston, M.D.  
Robert J. White, M.D.  
Andrew K. Worthington, M.D.  
Alan S. Zacharias, M.D.

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David D. Meyer, M.D.  
G. Franklin Crowell, M.D.  
Travis Harold Jackson  
Paul Martin, M.D.  
Thomas Mascenik, M.D.

NEUROLOGY ASSOCIATES OF  
GREENVILLE, P.A.

Kent Kistler, M.D.  
L Breeden Hollis, Jr., M.D.  
Benjamin R. Millar, M.D.  
D. Courson Cunningham, Jr., M.D.

BAY AREA NEUROLOGY, P.L.L.C.

Larry W. Blum, M.D.  
Damanhuri D. Alkaitis, M.D.

CHATTANOOGA NEUROLOGY  
ASSOCIATES, P.L.L.C.

Hytham A. Kadrie, M.D.  
Sharon N. Farber, M.D.  
Adele B. Ackell, M.D.  
Thomas G. Devlin, M.D.  
Matthew H. Kodsi, M.D.  
Tareck A. Kadrie, M.D.

**Waiting game plagues world-renowned hospital**  
**Financial problems threaten health care at public facilities**

The Associated Press

Updated: 4:49 p.m. ET Sept. 7, 2004

DALLAS - Adam Fira found himself in a hospital room after a car crash last year with half his skull missing and his head sunken in like a deflated basketball.

The high school football player couldn't run, lift weights or wrestle with his sisters. The slightest bump or fall could harm his brain, protected only by skin etched with a road map of pink scars.

For months, he wore a skateboarding helmet to school and waited for doctors at Parkland Memorial Hospital to schedule surgery to implant a plastic skull.

Doctors said it might happen before Christmas, but it didn't. When it was delayed again in May, the handsome, popular athlete lost confidence. He stopped talking to friends. He stopped leaving the house.

Finally, on July 12, the phone rang. Parkland had scheduled surgery for the next morning. Fira's mother used up her cell phone minutes spreading the news to family, coaches and church members. Her son couldn't sleep that night. His stomach churned like it used to on Fridays before the game. Before dawn, they drove two hours from the small town of Hillsboro to Parkland.

In room 229, his black curls shaved, stomach empty, an IV in his arm and 15 relatives camped out nearby, Fira waited for his new skull.

Hours went by. Noon passed. Another soap opera droned on TV. Fira grew more hungry and frustrated the longer he waited.

After 13 hours, doctors told him to go home. Another patient's aneurysm and other emergencies at the public hospital had tied up doctors and operating rooms all day. Fira's surgery, considered elective, would just have to wait.

"I didn't want to believe them," said Fira, now 18. "I could have exploded, but that wouldn't have done anything."

Fira's experience is a common one at Dallas County's only public hospital, even though he is among the 7 percent of its patients with insurance. That makes him one of the few paying customers of a hospital in desperate need of more money.

Because Parkland doctors saved his life, Fira's parents wanted his surgery done there. Financial crisis persists at public hospitals. The financial crisis that erodes patient care and, some doctors say, threatens lives at Parkland is part of a larger crisis threatening to unravel safety net health care at many of the 1,100 public hospitals across the country. Since their origins in the 1700s as almshouses and sanitariums, public hospitals have relied on taxpayer dollars to provide care to Americans who couldn't afford it otherwise. Some, like Parkland, branched out over the years, teaming with medical schools to become state-of-the-art teaching institutions that draw patients who could afford to go elsewhere. In some cases, public hospitals offer the only top-level trauma or burn care in a region.

But in recent years, public hospitals have been hit hard by government health cuts, just as surging numbers of uninsured Americans and illegal immigrants are turning to them for care. Nearly 82 million people — one-third of the U.S. population under 65 — lacked health insurance at some point over the past two years, according to a recent study by Families USA, a private consumer group. Texas had the highest rate in the nation, with more than 43 percent of its non-elderly population uninsured.

The National Association of Public Hospitals and Health Systems says about half of its 100-plus members lost money in 2002, the latest data available. Many are cutting jobs, shuttering clinics and postponing surgeries to keep the doors open.

"The situation, which is generally always grim, is even grimmer now," said Rick Wade, a spokesman for the American Hospital Association. "You look at every part of the public health care system and you see enormous strain and you see everybody hollering for help. And the answer is unclear." And patients, it seems, are paying the price. No room for patients

At Parkland, which delivered nearly 16,000 babies last year, women are giving birth in the hallways. In the emergency room remembered across the nation as the place where President Kennedy was taken after he was shot, patients without life-threatening injuries wait an average of 7½ hours for care. They get in line before dawn to pick up prescriptions.

A woman with a lump in her breast can wait three months for a biopsy. Dying cancer patients are spending their last days waiting up to 10 hours for chemotherapy in a cramped room where some sit in office chairs for lack of recliners. In the operating room, which does about 15,300 surgeries per year, patients wait eight months for gall bladder surgery.

Like triage on the battlefield, doctors and nurses ration the hospital's shrinking resources and space. They take care of the car crashes, the gunshot victims, the patients closest to death and they put off the rest. "Anything that can be delayed will be delayed," says Dr. Ron Anderson, Parkland's CEO for 22 years.

Parkland is the primary teaching facility of the University of Texas Southwestern Medical Center at Dallas, which touts four Nobel laureates, more than any other medical school in the world. And, under Anderson's leadership, Parkland has made U.S. News & World Report's best hospitals list for the past 11 years.

The quality of the staff remains the best, Anderson says, and many patients agree. But Anderson believes Parkland is facing the most dire moment of his tenure. Without new funding, patient care will suffer, along with the hospital's proud reputation.

Parkland and its clinics reported more than 849,000 patient visits last year. Ninety-three percent of those treated had no private insurance — nearly 40 percent couldn't pay, and the rest were on Medicare or Medicaid. About 4 percent of Parkland's \$812 million operating expenses went toward unpaid medical bills of patients from nearby counties without public hospitals. The Parkland system

also lost about \$74 million in state and federal funding for 2004-05. To help compensate, it eliminated about 500 jobs.

Still Parkland refuses to turn patients away. "Sometimes, the crisis isn't in public view. It's pushed downstream, but nevertheless, it happens and I think it's time to tell people," Anderson said. "There's a point where it's going to become unsafe. It already has in some ways."

The waiting game

Paula Holland would agree. She's been waiting more than a year to have a brain tumor removed.

Holland said doctors told her that the mass woven deep beneath her long silver hair has coiled itself around a band of nerves above her neck, strangling her vocal chords and pinching her voice to a rasp. Her headaches get worse. She can't remember easy things, like her sister's longtime phone number. If she doesn't have surgery soon, doctors told her recently, it could affect her hearing and swallowing.

Doctors at a private hospital in Dallas discovered the tumor and another one behind her eye in October 2002 after she nearly died from a brain aneurysm. They referred her to the neurosurgeons at Parkland, who removed the tumor behind her eye, but haven't gotten to the other one.

"It's always something. One thing or another. They keep putting it off," said Holland, a 47-year-old former volunteer firefighter. "It's mentally draining."

Over the past year, Holland said she has seen about 20 doctors in several different Parkland clinics. She waits five, maybe six hours each time to spend 10 minutes with a doctor who always seems rushed.

"It's kind of like cattle. They run you in and run you out, except you wait for hours in between." They say she needs surgery and suggest it's coming soon. They'll call, they say. But seldom do. She'd like to go somewhere else, but she lost her private insurance, and as a Medicaid patient, her options are few.

"Put yourself in my shoes: They tell you have a brain tumor and the first thing that enters your brain is 'oh my God, I'm going to die,'" Holland said. "Then they tell you they're going to set a date and then they don't."

A hospital official familiar with Holland's case said doctors would have operated sooner if the tumor were growing rapidly or threatening her sight, but its size hasn't changed much. Meanwhile, the monster living in her head is a mystery. She doesn't know how big it is or how long it's been there.

The hardest part is she won't know if it's cancer until they operate.

"I try not to think about that," she says, hiding her tears with her hands. "I just try to think it's not going to be cancer."

Many depend on public care. Paulette Cano knows the cancer has already won.

The tiny 62-year-old with curly gray hair waits for her chemotherapy. By the time she came to Parkland in late 2002, she was terminal. She'd like to spend her time left planting flowers, reading Dean Koontz or enjoying her very own tub of Blue Bell ice cream. Instead, she's in a row of cancer patients, waiting

sometimes 10 hours for her chemotherapy treatment. "You know you're going to die," Cano says. "And you're losing a whole day basically just waiting."

The former legal secretary lost her health insurance when she could no longer work. Now on Medicaid, she said Parkland is her only option.

It takes only 15 minutes for the drugs to flow from the clear bag into her frail body, hunched in an office chair with rollers. And the nurses are good.

"These ladies, bless their heart, they're falling all over themselves because there's no room for us," she says.

The chemo is supposed to buy her time and keep her comfortable. But she's losing time in the process.

"It kind of makes me mad because I worked since I was 15 and paid taxes and probably helped build the first Parkland," she says. "I think, 'you know, it's my turn. Why can't they do something for me?'"

Going elsewhere

Fira, the teenager waiting for skull surgery, could have gone elsewhere. But his mother, Christina Lopez, wanted the surgeons who started the job to finish it. She understood the hospital's need to treat life-threatening injuries first, but it made her angry that the hospital considered her son's surgery elective.

After Parkland rescheduled the surgery in July — another false start — Lopez got her son referred to a private hospital. The next day he was in surgery at Zale Lipshy University Hospital, down the road from Parkland.

"They got in there. They got the job done," said Fira's mother.

Though she still raves about Parkland's trauma care, she regrets not going to a private hospital sooner.

Fira's now back at school, a few weeks into his senior year. He's lifting weights, running a bit and trying to get in shape to play basketball this season.

"For the past year, we've had Adam, but we haven't really had Adam," Lopez says. At least now, "Socially, he's himself again. He's not ashamed in any shape or form."

She just wishes he could have gotten there sooner.

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URL: <http://www.msnbc.msn.com/id/5900349/>

## **Medicare cancer drug cuts double estimates Proposed payments inadequate, survey of doctors shows**

The Associated Press  
Updated: 12:31 p.m. ET Sept. 8, 2004

WASHINGTON - Proposed cuts in Medicare payments for cancer drugs will be nearly double Bush administration estimates, potentially limiting access to care, according to a survey of cancer doctors.

Payments from the government for some drugs will not equal the cost to most doctors, the American Society of Clinical Oncology said Wednesday. It has lobbied to restore funding that would be cut under last year's Medicare prescription drug law.

The average reduction in reimbursement for the medications will be 15 percent, according to the group's analysis of pricing information provided by community oncology practices. The administration said the cuts would not exceed 8 percent on average.

Cancer doctors have said the proposal could put some practices out of business, forcing patients to get their treatment in hospitals, sometimes far from their homes.

"We believe it is not only our responsibility as oncologists to provide quality care, but also to let Congress and policy-makers in Washington know that these cuts may be more significant than intended," said Dr. Margaret Tempero, the group's former president.

Proposed changes announced in July would save the government \$530 million and Medicare beneficiaries \$270 million next year, said Dr. Mark McClellan, administrator of the Centers for Medicare and Medicaid Services. Medicare spent \$10.5 billion last year on prescription medicines administered in physician offices and clinics.

The government has been paying the physicians up to twice what they should for certain medications, the administration said. Yet the government allowed the overpayments to continue because it acknowledged that doctors were underpaid for their practice expenses, such as nurses, equipment and treatment rooms.

McClellan said Wednesday that Medicare is working with cancer doctors and plans to add payments for administering the drugs, partly addressing their concerns. "The numbers and the impact are not included at all," in the ASCO study, McClellan said in an interview.

ASCO officials said the government has yet to make available information on those payments.

The doctors' group said its survey found several drugs for which proposed reimbursements are inadequate.

## **System out of whack**

Three-quarters of cancer practices will spend more than Medicare will reimburse for epoetin, used to treat anemia, which is common among cancer patients, the survey found. The Medicare reimbursement for pamidronate, used for bone metastasis, won't cover the costs for 70 percent of practices.

More than half of cancer doctors say they will spend more than they are reimbursed for irinotecan, a treatment for colon cancer, and gemcitabine, used for lung and pancreas cancers.

Medicare won't pay for most prescription medicines until 2006, but it covers the cost of intravenous chemotherapy and other treatments that must be dispensed by medical professionals.

Doctors have long acknowledged that the payment system has been out of whack for cancer care administered in their offices. Several studies have documented that drug reimbursements were tied to an inflated price rather than to what doctors paid. The Medicare law called for the system to be fixed.

Cancer specialists and patient advocates have asked Congress essentially to freeze payments at current levels until various agencies complete studies of the new pricing system, expected in 2006.

Ketchum Communications, the public relations company working with the cancer doctors to call for a change in the Medicare law, also is the principal contractor employed by the administration to promote that same law.

The administration has spent \$87 million on television ads, mailings and other means to promote the new law, most of it to tout prescription drug coverage that will be available through Medicare in 2006, the Health and Human Services Department said.

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Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Desparately need a change in rural designation for Santa Cruz County (current locality 99). Reimbursement rates are 25% lower than our neighboring county 20 miles away for the same services performed by local physicians. See attached letter.

CMS-1429-P-3556-Attach-1.doc

CMS-1429-P-3556-Attach-2.doc



# County of Santa Cruz

## LONG TERM CARE INTERAGENCY COMMISSION

1400 EMELINE AVE., 3rd FLOOR, SANTA CRUZ, CA 95060  
(831) 454-4864 FAX (831) 454-4290  
LARRY FRIEDMAN, CHAIR

September 21, 2004

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore MD 21244-8012

SUBJECT: File Code CMS 1429-P RE: GPCI

On behalf of the Long Term Care Interagency Commission, I am writing to provide comment on the issue of Physician Payment Localities. The Long Term Care Interagency Commission serves as the community long-term care task force and monitors legislation and long-term care service delivery to Santa Cruz County and makes appropriate recommendations regarding these services. In meetings of the Commission we have discussed the issues related to the lack of physician accessibility in the Santa Cruz area for our local seniors under Medicare. This is a very serious problem.

The elderly of Santa Cruz County share in the nationwide problems of funding and accessibility of health care. What is becoming increasingly disturbing is also the additional problem of the diminishing pool of available Medicare physicians in the community for primary, secondary and tertiary care. Many seniors who require recovery and/or rehabilitation in a skilled nursing setting are finding that their regular physician will not follow them to the skilled nursing setting due to the added time and low Medicare reimbursement. The trauma experienced due to placement is further intensified by the unfamiliar medical attention, often causing a longer and more costly recovery or rehabilitation period. At the same time, the skilled nursing facilities in the County are struggling to survive due to rising costs and low reimbursement rates.

The "rural" classification designated to Santa Cruz County (current locality 99) reimbursement rates for physicians under the Medicare Reform Bill of 1996 means that those reimbursement rates are lower than in neighboring California counties. In fact, the payment differential for physician services in a county less than 20 miles from ours is over 25% greater than for services performed by local physicians. We understand that this is by far the greater such differential in the country.

The County ranks among the highest in California and the nation in which to live. The discrepancy in reimbursement rates and the economics of the area have resulted in many physicians actually leaving, others refusing new Medicare patients, and many actually opting out of participation in HMOs and Medicare. Recruitment of new physicians treating the older population is reaching a crisis level. Finding

physicians who are willing and able to meet seniors' medical needs is becoming more and more difficult.

Because the CMS has a commitment to review localities in multiple locality states if newer GPCI data indicates dramatic cost changes, the Commission highly recommends that you take the opportunity to implement the following changes immediately:

- Physician reimbursement rates for our county should be based on actual costs as determined by CMS
- Acute, sub-acute and skilled nursing facility reimbursement rates for our county should be based on actual costs as determined by CMS

These actions are necessary to increase the numbers of physicians willing to treat the Santa Cruz County Medicare population. Without the availability and accessibility of quality medical care in our County, the seniors are at great risk of not only declining health status, but increased preventable dependence upon higher levels of care. Thank you for your commitment to quality Medicare and Medicaid services and for the opportunity to provide this request for changes to our rural status.

Respectfully submitted,

Larry Friedman,  
Chairperson

cc: Santa Cruz Board of Supervisors  
Cecilia Espinola, Human Resources Agency Director  
Rama Khalsa, County Health Services Director



# County of Santa Cruz

## LONG TERM CARE INTERAGENCY COMMISSION

1400 EMELINE AVE., 3rd FLOOR, SANTA CRUZ, CA 95060  
(831) 454-4864 FAX (831) 454-4290  
LARRY FRIEDMAN, CHAIR

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Larry Friedman,  
Chairperson

cc: Santa Cruz Board of Supervisors  
Cecilia Espinola, Human Resources Agency Director  
Rama Khalsa, County Health Services Director

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached file

Garth Babcock Ph.D., ATC  
2608 Wheaton Ln  
Cheney WA, 99004

9-23-04

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: Therapy – Incident To

Dear Sir/Madam:

I am writing to express concern over the recent proposal that would limit providers of “incident to” services in physician clinics. The stated limitations within the proposal eliminate some highly qualified health care professionals who currently provide these important services. Eliminating these professionals, will reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

During the decision-making process, please consider the following:

Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of their patients.

In many cases, the change to “incident to” services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible healthcare. The patient would be forced to see the physician and separately seek

therapy treatments elsewhere, causing significant inconvenience, a possible decrease in quality of care, and additional expense to the patient.

This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.

Patients who would now be referred outside of the physician’s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient’s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

Restricting to whom the physician can delegate “incident to” procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician’s ability to provide the best possible patient care.

To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

In an independent research study the quality of services provided by certified athletic trainer was demonstrated to be equal to the quality of services provided by physical therapists. Further, athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to neglect to include and therefore “suggest” that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is unjustified.

Two final concerns include first, that the CMS, in proposing this change, offers no evidence that there is a problem that is in need of being fix. And second, that the CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” a physician office visit.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation, in my mind is a health care access deterrent.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Good Day,

I am a pain management physician in a small town. I or my well trained nurse practitioner will perform physical therapy treatments to include cold or heat treatments, myofascial release, joint adjustments, education on stretching and strengthening, and or traction for patients that have had an injection or are acutely in pain. We do not have access to a PT nor an OT in the clinic. My nurse practitioner's and my training meet or exceed a therapists in these areas. Our patients would not be receiving quality and timely care if they had to wait for approval for a PT or OT visit (2-3 days) and then wait for an appointment ( up to a week) to receive these treatments.

Certainly we use therapists for extensive therapy however they are not needed for more simple treatments that are needed acutely. There is also a cost savings because a therapist's full evaluation (\$100-200) would not need to be performed prior to therapy. The doctor or nurse practitioner would already have performed an appropriate exam.

Thank you for your time and your consideration.

C. Tracy Muscari, MD

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Dear Sir/Madam:

I am writing with regards to the recent proposal that would recommends a change to Medicare regulations no longer allowing physicians to be reimbursed for the therapy services that may be administered by an athletic trainer. If this proposal were to be adopted, therapy services given by an athletic trainer would not be reimbursed by Medicaid, only those of a physical therapy, a physical therapy assistant, an occupational therapist or occupational therapist would be reimbursed. Due to similar trends among insurance companies, this means that athletic training services may not be reimbursed by any clinical settings.

As an athletic trainer, an individual is trained to evaluate, treat and rehabilitate various injuries that may occur during athletics or during work activities. Athletic trainers are trained in rehabilitating athletes back from injury and returning them to their full potential abilities. This is not only an issue in competitive sports, but also in the clinical and industrial settings, to improve the acts of daily living of an individual and returning them to work ready and prepared to take on their daily tasks. Athletic trainers work under the supervision of a physician in general physician offices, non-athletic locations, athletic training rooms, and sports medicine clinics. Not only do athletic trainers specialize in rehabilitation of sports injuries, but also in recovering from non-sport related injuries such as overuse injuries. The amount of training that an athletic trainer generally has in the area of injury rehabilitation is generally equally or more qualified than a PT, OT, PTA, or OTA. Classes that an athletic trainer takes are often the same classes as a PT would take or are similar classes. Not only do athletic trainers have to pass the NATABOC exam, but they are also required to enhance their education by participating in continuing education courses.

In conclusion, the education of an athletic trainer is regarded by the federal government as equivalent to a PT's, and it is more significant than an OT, PTA, or OTA. Please keep this in consideration as you contemplate the proposed Medicare changes. Thank you.

Submitter :  Date & Time:

Organization :

Category :

#### Issue Areas/Comments

#### Issues 10-19

##### SECTION 952

I wish to applaud the change in supervision status for PT Assistants in Private Practice settings. It is moving in the right direction. However, with further investigation into all our 50 state's supervision requirements for patients in a mobile, out-patient setting; it will be clear that "General Supervision" is most usually required.

I have been a PTA for 3 years, and before that had a 27 year career in public relations and marketing with a bachelor's degree from UC Berkeley. When I look at current Medicare supervision rules, I can't help but notice the inconsistencies.

Supervision of the PTA is not specifically delineated for in-patient or out-patient PT services--so those sites are governed by state practice law. In many of our states, that is "General Supervision". Yet if I look at out-patient private practice, the new level of supervision is only "Direct". The PT's in each of the out-patient settings are licensed--the only difference is the type of company that owns the clinic. The patients are all more ambulatory, and independent than in any other practice setting (including SNF, that requires only "General" supervision"). Why would PTAs in a privately owned out-patient clinic require "Direct" supervision for safe and appropriate provision of PT services, when those PTAs in a hospital owned clinic (may be many miles from the hospital), are somehow more "competent" as they are only required to have "General" supervision.

To really be consistent, Medicare supervision rules should provide for "General Supervision" in all patient care settings, unless state practice law requires a more stringent level. Those levels do vary in some states, and the reason may be a PTAs lack of licensure in many of them. Most states now require licensure for PT Assistants, because it is the best way to protect the public: ensuring that properly educated, competent individuals are providing physical therapy services. In states where licensure is required, the overwhelming rule of supervision in all patient settings is "General".

Thank you for your time and consideration in this matter. I serve as an advocate for the best overall healthcare for all of my patients, and I would be remiss, if I did not pursue this through all avenues.

Sincerely,  
Sandra J Molhoek, BA, PTA  
Oregon,  
sandy33@verizon.net

#### Issues 20-29

##### THERAPY - INCIDENT TO

I wish to comment on the August 5 proposed rule on ?Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.? I support CMS's proposed requirement that physical therapists working in physicians offices be graduates of accredited professional physical therapist programs.

I have a bachelor's degree (1972-Phi Beta Kappa, Magna Cum Laude from UC Berkeley: an avenue into a 27 year career in public relations and marketing. I am now a Physical Therapist Assistant, with 3 years in out patient orthopaedic practice. From my extensive experience in the business world, I have learned that honesty and integrity with the customer is essential. Misrepresentation of any kind undermines trust, is harmful to outcomes, and is not financially productive in the long run.

Physical therapists and physical therapist assistants, under the supervision of physical therapists, are the only practitioners who have the education and training to furnish physical therapy services. Unqualified personnel should NOT be providing physical therapy services. Our senior population counts on Medicare to help them receive safe and effective medical care, so it would be most appropriate to also require licensure as a standard for these professionals. Licensure is a commonly accepted standard in our society to achieve proper protection of the public.

Physical therapists must be licensed in the states where they practice. As licensed health care providers in every jurisdiction in which they practice, physical therapists are fully accountable for their professional actions. Physical therapists receive significant training in anatomy and physiology, have a broad understanding of the body and its functions, and have completed comprehensive patient care experience. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation. This education and training is particularly important when treating Medicare beneficiaries.

The delivery of so-called ?physical therapy services? by unqualified personnel is harmful to the patient. There is no physical therapist

**CMS-1429-P-3560**

evaluation performed, and no overall treatment plan, with short and long-term goals. Palliative modalities may be performed, but the training for provision of these services is questionable. The most essential part of "Physical Therapy" is most frequently missing:

- 1) Education in an individually contoured and properly performed home exercise program, with transition to a maintenance program for continued mobility, and strength to protect against re-injury.
- 2) Education in proper body mechanics for performance of ADL's and work activities. Again, for prevention of re-injury, or new injury.
- 3) Patient understanding of the need to take personal responsibility for participation in their own health outcomes: follow through with exercise, posture, body mechanics etc.

A financial limitation on the provision of therapy services (the therapy cap) is scheduled to become effective January 1, 2006. Under the current Medicare policy, a patient could exceed his/her cap on therapy without ever receiving services from a physical therapist. This will negatively impact patient's outcomes. This will then negatively impact Medicare's finances. Patients will require continued appointments for the "palliative care" received from non-PT providers. Without posture and body mechanics education and performance training, patients will have to return again and again secondary to re-injury... It will be a continued financial burden.

In closing, I wish to thank you for your time and consideration. I know that CMS is making every effort to provide comprehensive, safe and effective medical care for its beneficiaries.

Sincerely,

Sandy Molhoek, BA, PTA

Oregon

sandy33@verizon.net

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please do NOT pass this policy, restricting a physician's referral of "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physician's prescription, or under a physician's supervision.

Thank you.

Sincerely,  
Lynn Leyda, CMT, NCBTMB, ABMP

If you wish to REPLY, reply to : "lynnleyda@hotmail.com"

Submitter : Miss. Michelle Groves Date & Time: 09/23/2004 11:09:41

Organization : Individual response

Category : Individual

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am currently enrolled in a Physical Therapy Assistant program in the state of Ohio. I would like to comment on the proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." I am expressing strong support of CMS's proposed requirement that physical therapists working in physician's offices be graduates of accredited professional physical therapist programs. What has started as a 2 year program has taken me 4 years to complete. It has been difficult and exhausting but I have cherished every moment. I don't feel it fair for someone else to provide the services that I was trained to do. Physical Therapist and Physical Therapist Assistants under the supervision of physical therapist are the only practitioners who have the education and training to furnish physical therapy services. Anyone personnel who is unqualified should not be providing physical therapy services.

Thank you Mark B. McClellan, MD, PhD for considering my comments.

Sincerely,

Michelle Groves

Submitter : Mrs. Annette Steiner Date & Time: 09/23/2004 11:09:28

Organization : Individual response

Category : Individual

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am currently enrolled in a Physical Therapist Assistant program in the State of Ohio. I wish to comment on the August 5th proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calander Year 2005." In the proposed rule, CMS discusses establishing requirements for individuals who furnish outpatient physical therapy services in physician's offices. CMS proposes that qualifications of individuals providing physical therapy services "incident to" a physician should meet personnel qualifications for physical therapy in 42 CFR 484.4, with the exception of licensure. This means that individuals providing physical therapy must be graduates of an accredited professional physical therapist program or must meet certain grandfathering clauses or educational requirements for foreign trained physical therapists. I am going to school for two years to get my license. I believe that since I have been properly trained and will have a license that I should be the only one that should provide physical therapy services.

Thank you Mark B. McClellan, MD, PhD for considering my comments.

Sincerely,

Annette Steiner

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

I personally have received physical relief from cranial-sacral therapy, relief that would not have been received any other way. I also utilized deep-tissue therapy to lessen neurophy pain caused by chemotherapy.

Thank you for your consideration.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005-

I am a physical therapy student that will graduate in May, 2005 with a Doctorate in Physical Therapy. I will be entering the field of physical therapy in the very near future and have concerns regarding the 'Therapy-Incident To' policy. I would like to comment on the August 5 proposed rule on Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. I strongly support the proposition to require individuals providing physical therapy services 'incident to' a physician to be a licensed physical therapist. After studying and preparing to enter the field of physical therapy over the last three year in an accredited physical therapy program, I feel I have the knowledge and tools to safely provide physical therapy treatment to any patient. However, without the education and clinical experiences I have gained, I do not feel that physical therapy services could be performed in a safe, effective manner. I feel it is dangerous and not in the patient's best interest to have an unqualified individual provide such services. Thank you for your time.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached file

Dear Sir/Mam,

- I am:
1. a taxpaying American Citizen.
  2. The United States of America is a country founded by the people for the people.
  3. an individual who has paid into the Medicare system for twenty years.
  4. the son of a parent and in-laws to citizens who are in the process of retiring and entering medicare eligibility.
  5. a four-year college educated professional with a national certification and state licensure.
  6. fighting for my livelihood and ability to pay my taxes and support my family.
  7. the former clinician to patients who are very confused and frustrated.
  8. a voter who votes in EVERY election.

I am very displeased that members of the APTA(American Physical Therapy Association) are so shortsighted and greedy enough to lobby to put colleagues out of work and limit the amount of experience that there patients will receive.

Please keep the options open for those citizens who have paid into the system, who deserve the best care possible, and who have made this country what it is.

Michael A. Cirino ATC, NSCA-CPT  
34640 W. Sharondale Dr.  
Solon, Ohio 44139  
(440) 248-7240

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I oppose medicares proposed policy to eliminate any provider except physical therapist from providing "incident to" medical professionals services to patients.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Restricting access to any of the many avenues of health care will seriously undermine the ability for patients to access the best of care that is available for the American people. It is imperative that all qualified health care providers be allowed to provide services to patients with a physicians prescription or under their supervision. Please do NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. Thank you for your involvement in this serious concern. Bobbi Stutsman, H.H.P.

Submitter :  Date & Time:

Organization :

Category :

Issue Areas/Comments

**GENERAL**

GENERAL

I oppose the section which would prevent physicians from referring patients to massage therapists.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Here is a letter in response to the "incidnet" to services.

Sincerely,

Jeannie Rojas, SPT

Jeannie Rojas  
50 Park Ave.  
Passaic Park, NJ 07055

February 3, 2005

To whom it may concern:

My name is Jeannie Rojas; I am currently enrolled in the Doctorial program of Physical Therapy at the University of Medicine and Dentistry of New Jersey. As student physical therapist's we are made aware of several issue which in some sort are related to our future profession. The latest issue which has be brought to our attention is that of physical therapy services, which is certain locations is not being provided by physical therapists.

The following letter is to express my full support with regard to the proposed personnel standards for physical therapy services that is being provided in a physician's office. Services that are rendered to clients/patients and billed as physical therapy services should be carried out by a licensed physical therapist. If quality of care is the motto of the health service industry, it would only make sense that physical therapy should be performed by physical therapists, it is what we are qualified to do.

Physical therapists have an educational standard, as well as, a licensing exam very different in comparison to other health care professionals, which proves our competence in the field of physical therapy. Therefore, it should be of no debate that physical therapy should be preformed by physical therapist.

Sincerely,

Jeannie Rojas  
SPT

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Do Not pass this policy whereby a physician can only refer "incident to" services to physical therapists. All health care providers ought to be able to provide services to patients with a physicians referral/perscription for treatment.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I am strongly opposed to the proposed policy which eliminates all healthcare providers except Physical Therapists from providing "incident to" medical professionals' services to patients. Many such providers, and especially Licensed Massage Therapists, are highly trained and highly regarded professionals whose expertise supports the primary treatment offered by medical professionals. There are numerous medically appropriate situations and conditions where such other modalities promote healing and enhance health. The opportunity to provide such services should not be limited a single modality or professional designation. Such a limited approach reduces rather than expands the resources available to medical professionals for medically- and cost-effective treatment.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Nicole Schwab  
1995 E. Coalton Rd.  
#54-102  
Superior, CO. 80027

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Medicare Program; Revisions to Payment Policies Under the Physicians Fee Schedule for Calendar Year 2005

My name is Nicole Schwab and I am currently a physical therapist student, finishing up my last year of studies at Regis University in Denver, Colorado. In May 2005, I will graduate with a Doctor of Physical Therapy degree.

I am writing in regard to the August 5 proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." I would specifically like to address the "therapy-incident to" issue concerning the implementation of standards for personnel providing physical therapy services within physician offices. I am in support of the proposed rule by CMS that requires the delivery of outpatient physical therapy services in a physician's office be provided by individuals who are graduates of an accredited professional physical therapist program.

My position is from a student's standpoint that has experienced the extensive education and training that is necessary to perform the skills of a physical therapist. My studies on management of the human body, that includes understanding of body kinematics and rehabilitative techniques, enables me as a therapist to provide optimal care for my patients with disabilities and injuries. My education has molded me into an expert in the field of physical therapy to deliver services for patients requiring rehabilitation that another professional without the same education cannot provide.

Hundreds of students each year put in an immense amount of time and effort to complete the minimum educational requirements established in January 2002 that requires a post-baccalaureate degree from an accredited program. The Commission on Accreditation of Physical Therapy accredits physical therapist programs, an independent agency recognized by the U.S. Department of Education. Those who provide physical therapy services without the appropriate qualifications are not only insulting the profession and those who have accomplished the comprehensive training, but are also in violation of section 1862(a)(20) of the Social Security Act. It is outlined in the act that in order for a physician to bill "incident to" for physical therapy services, those services must be performed by persons who are graduates of an accredited professional physical therapist program. These requirements are the same for outpatient therapy services in all settings. Furthermore, physical therapy services delivered by unfit personnel have the potential to harm patients. Many individuals come into the clinic as complex cases that require a differential diagnosis. As a doctor of physical therapy I have been educated to accurately identify complex cases and proceed with the proper plan of care. Failure to recognize critical signs and symptoms, misdiagnosis, or implementation of an inappropriate treatment may be fatal to the patient.

To further ensure that no patient is harmed from the services rendered by personnel without the proper education, I must emphasize the value of agencies requiring licensure from persons wishing to provide physical therapy services. It holds professionals accountable for their actions and should be considered as a standard to prevent unqualified individuals from delivering physical therapy services.

In closing, I would like to thank you, Mark B. McClellan, MD, PhD for the time you have taken in consideration of my position on this matter.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Limiting the general public's choice for health care provisions to physical therapists only is very limiting. Massage Therapist, Chiropractors, and Acupuncturists, to name a few, are extremely helpful and produce consistent results of health improvement. I personally as a Licensed Massage professional have helped several clients whom had gone through Physical therapy with little improvement. After visiting me they have regained full range of motion and reduced pain. Such limiting legislation reflects the ignorance of understanding the human body's physiology and it sounds as if Physical Therapists are trying to secure the corner on the market. Thank your constitutional rights that your choice for example on motor vehicles is not limited to just one company, so when it comes to the most important vehicle you have, your Body, why then should you limit your choices of providers. I believe all qualified health care providers should be allowed to provide services to patients with a physician's prescription or under their supervision.

Thank you,  
Michael King L.M.T.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please DO Not pass this policy allowing physicians to refer "incident to" services only to physical therapists. ALL QUALIFIED health care providers should be allowed to provide services to patients with a physicians' prescription or supervision

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I would like to register my opposition to the proposed legislation. As it is written only one group (physical Therapist) will benefit from this. PT although being one source of therapy is far from being the only source. Our patients have a variety of needs where therapy is done on an individual basis, many are less expensive than PT. The bottom line is providing the right treatment to the patient.

Submitter : Mrs. Tracey Goff Date & Time: 09/23/2004 11:09:41

Organization : Mrs. Tracey Goff

Category : Physical Therapist

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

To whom it may concern:

I would like to comment on the proposed rule on "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005." I am a licensed physical therapist practicing for seven years in an out patient rehabilitation center as part of a hospital.

I believe the delivery of "physical therapy services" by unqualified personnel can be harmful to the patient. Many of these health care professionals do not possess the expertise to safely and properly perform modalities they are classifying as physical therapy, as well as, understand the physiological ideas that support the therapy. It is unfair to the public to be charged for a physical therapy service that is not performed by someone with a physical therapy degree, trained to carry out the task. Currently, degrees in physical therapy are at the post "baccalaureate level with all accredited schools offering a master's or doctor of physical therapy degree.

I also believe many patients are unclear of their benefits and how the medical services they receive are billed. It is unfortunate a patient may arrive at a clinic to receive physical therapy services by a licensed physical therapist, only to discover they have already used a portion of their allotted visits or funds toward payment of physical therapy. Patients become frustrated with the system because they do not understand why "physical therapy services" are exhausted when they haven't even stepped foot into a physical therapy clinic.

I believe the current method of billing of "incident to" services is a poor reflection of our credibility as professionals and eventually limits the patient from receiving appropriate and justified physical therapy when needed. With the patient's best interest in mind, I would like to show support to CMS's proposal.

Thank you for your consideration of these comments.

Sincerely,

Tracey Goff, MPT

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Dear Mr. McClellan:

I would like to comment on the proposed rule on “Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005.” I am a licensed physical therapist practicing for seven years in an out patient rehabilitation center as part of a hospital.

I believe the delivery of “physical therapy services” by unqualified personnel can be harmful to the patient. Many of these health care professionals do not possess the expertise to safely and properly perform modalities they are classifying as physical therapy, as well as, understand the physiological ideas that support the therapy. It is unfair to the public to be charged for a physical therapy service that is not performed by someone with a physical therapy degree, trained to carry out the task. Currently, degrees in physical therapy are at the post –baccalaureate level with all accredited schools offering a master’s or doctor of physical therapy degree.

I also believe many patients are unclear of their benefits and how the medical services they receive are billed. It is unfortunate a patient may arrive at a clinic to receive physical therapy services by a licensed physical therapist, only to discover they have already used a portion of their allotted visits or funds toward payment of physical therapy. Patients become frustrated with the system because they do not understand why “physical therapy services” are exhausted when they haven’t even stepped foot into a physical therapy clinic.

I believe the current method of billing of “incident to” services is a poor reflection of our credibility as professionals and eventually limits the patient from receiving appropriate and justified physical therapy when needed. With the patient’s best interest in mind, I would like to show support to CMS’s proposal.

Thank you for your consideration of these comments.

Sincerely,

Tracey Goff, MPT

Submitter : Mrs. Carol Benn Date & Time: 09/23/2004 11:09:59

Organization : American Massage Therapy Association

Category : Other Health Care Professional

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dear Sirs;

I feel that massage therapy and other forms of body work should be an accepted part of your program. It can assist in the recovery from injury often without the use of drugs.

Sincerely,

Amy Bidwell  
LMT

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached file.

September 19, 2004

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

To Whom It May Concern:

I am writing to show concern about a recent CMS proposal that was put forth for consideration. I am not only concerned for the current athletic trainers in the clinical setting, but I also fear for my future as an athletic trainer when I graduate from college if this proposal is accepted. As a student, I am being educated in the prevention, treatment and rehabilitation of injuries suffered to an athletic or active population. I am being prepared to do this by taking classes such as therapeutic modalities, rehabilitation, orthopedic assessment, and athletic medicine, all of which have physical therapy students enrolled. These classes will give me the nomenclature that I will need and more importantly the knowledge to rehabilitate the athlete. I also am required to pass a national certification exam and in some state's an additional state licensure exam in order to receive my license to practice. Through out my career, I will be required to take continuing education courses in order to keep my license as an athletic trainer. In reality, athletic trainers have a similar knowledge base and experience as a physical therapist except with a slightly different job description and in most, but not all, cases a different job location. According to the federal government, the preparation of an athletic trainer is equivalent to physical therapists, and is more significant than that of an OT, OTA or PTA. To me and many other athletic trainers, it does not make sense to no longer allow physicians to be reimbursed for therapy services administered by a certified athletic trainer, but allow reimbursement for PTs, PTA's, OT's, and OTA's, when we are put higher than three of the four. How does this look to the patient? We are trying to give them the best care possible; however, CMS is trying to limit their opportunity to be cared for by a highly qualified professional. The U.S. Department of Labor has even stated that the level of education, preparation required, and duties of an athletic trainer are higher than an OT, and two times higher than OTA's and PTA's. According to the NATA, athletic trainers are being hired more these days to work in a clinical setting or with certain businesses to rehabilitate patients and workers. By passing this proposal, the people who already work in these settings are going to be greatly affected, and may be even out of a job because doctors will not be willing to pay for something that they can be reimbursed for with a different, but equally or even more qualified professional. As far as my future is concerned as an athletic trainer, my opportunities to implement what I have worked hard to learn will be greatly limited. It does not make sense to deny reimbursement to a physician for services provided by athletic trainers when we are just as qualified, if not more than others, to do the job. Again, denying this reimbursement also denies the patient from obtaining the best care possible. Athletic trainers work hard to earn their license and stay up to date, so potentially taking away great opportunities

from such qualified professionals is in a way demeaning to athletic trainers and the patients who deserve the best. I hope that you reconsider passing such a proposal that will limit trained professionals from doing what they are taught to do and realize the impact that this may have on many athletic trainer's lives and more important the lives and health of all the patients affected by this.

Thank you,

Paige Cooper  
Baylor University Student Athletic Trainer  
Southwest Athletic Trainers Student Association Vice-Chair

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

MASSAGE THERAPISTS ARE HIGHLY QUALIFIED TO ADMINISTER THERAPY FOR CLIENTS IN THE SETTING OF DOCTORS OFFICES, CHIROPRACTORS OFFICES, AND THOSE UNDER THE DIRECTION OF HOSPITALS. WHAT A SHAME TO IGNORE THE HARD WORK OF OTHERS LIKE THOSE OF THE MASSAGE COMMUNITY IN THE PRACTICE OF TREATMENT FOR THE GENERAL PUBLIC.

Submitter : Mrs. Tina Merced LMT,NCTMB,CST Date & Time: 09/23/2004 11:09:50

Organization : Associated Bodywork and Massage Professionals

Category : Other Practitioner

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. If this policy passes, there may be a shortage of qualified providers of necessary treatments to medicare patients. For example, many Certified Lymphademic Specialist are operating under the authority of their massage therapy licenses.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Medicare needs to accept The massage professional as a separate group of professionals. The clients benefit fully and wholly from our manual care with side affects or pain. Medicare needs to realize the benefit of working with other health professionals and not to reject this group. Before PT and chiropractors were a strong group in congress, massage therapists worked in HOSPITALS as part of their training. Today it is a thing of the past thanks to the PTs is earlier years with jealousy. We need to work together for the full and positive benefit or our clients.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I understand that this rule will exclude massage therapy as an option for physician referral. It is a misconception that physical therapy provides the same treatment and benefit as massage therapy. Massage therapists are trained to correct muscle imbalances which contribute to chronic pain. As examples, neuromuscular therapy (NMT) addresses referred pain. Structural integration realigns the muscles which are causing posture problems, relieving pressure on joints. Not all physical therapists are aware of these techniques. Please reconsider disallowing massage thereapists as part of the total health team.

Submitter :  Date & Time:

Organization :

Category :

Issue Areas/Comments

**GENERAL**

GENERAL

Dr. Mark B. McClellan  
Administrator  
Centers For Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Dr. McClellan:

My name is Susan A. Dalaba, PT and I co-own an outpatient private practice in Cortland, New York with Susan D. Miller, PT, DPT, MS, OCS, Helen Duxbury, PT, and Alice C. Fadden, PT. We started our business in 2000 and as our business grew we eventually hired a physical therapy assistant (PTA) and another PT. One of the things that has always dismayed us as employers and as practitioners is the Therapy Standards and Requirements for the PTA in the outpatient private practice setting. In all the other settings that a PTA could work, whether it be a hospital, nursing home, home health, or a school, the PTA can provide services without the in-room supervision of a physical therapist.

My partners and I strongly support CMS's proposal to eliminate the requirement that physical therapists provide personal supervision (in the room) of physical therapist assistants in the physical therapist private practice office, and replace it with a direct supervision requirement.

PTAs have the education and training to safely and effectively deliver services without the physical therapist being in the same room as the physical therapist assistant. State licensure laws recognize the PTAs have the education and training to safely and effectively deliver services without the physical therapist being in the same room. No state requires personal (in the room) supervision of the physical therapist assistant.

In closing, I would like to thank you for your consideration of my comments. Should you have any questions or concerns, please feel free to contact me at the address or phone number listed below.

Sincerely,

Susan A. Dalaba, PT  
Fadden & Associates Physical Therapy, PLLC  
242 Port Watson Street  
Cortland, NY 13045  
(607) 758-7212

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

September 23, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
PO Box 8012  
Baltimore, MD 21244-8012

Re. Therapy-Incident To

Dear Sir/Madam:

The recent proposal that would limit providers of "incident to" services in physician offices and clinics is of great concern to me. If approved, this would eliminate the ability of qualified health care professionals to provide these important services. It would reduce the quality of health care for our Medicare patients and ultimately increase the costs associated with this service and place an undue burden on the health care system.

Please consider the following points:

? A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) who the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

? There have never been any limitations or restrictions placed upon the physicians in terms of who he or she can utilize to provide ANY "incident to" service. Private payers have always relied upon the professional judgement of the physicians to be able to determine who is or is not qualified to provide a particular service.

? Athletic trainers are highly educated. ALL certified or licensed athletic trainers must have a bachelor's or master's degree from an accredited college or university. Seventy percent of all athletic trainers have a master's degree or higher. Athletic training academic programs are accredited through an independent process by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) via the Joint Review Committee on educational programs in Athletic Training (JRC-AT).

? To allow only physical therapists, occupational therapists and speech and language pathologists to provide "incident to" outpatient therapy in physicians' offices would improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

? CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

? CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of therapy services.

? Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.

Insummary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care deterrent.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS ? 1429 ? P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

My name is Mike Severino and I am currently a final year, doctorate of physical therapy student at Regis University located in Denver, Colorado.

?Therapy ? Incident To?

I wish to express my opinion on the August 5th proposed rule regarding the 'Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005'. My interest in this issue deals with the necessary requirements that need to be established among individuals providing physical therapy services in an outpatient setting within physician's offices. Graduates of an accredited professional physical therapy program, certain grand-father clauses, or other educational requirements for foreign-trained physical therapists should only distribute individuals providing such services described as physical therapy.

I strongly believe and urge others to consider how necessary maintaining and enforcing the use of licensure helps preserve our professional integrity. It establishes a sense of consistency as well as implies a standard level of practice on all those under the title of physical therapist. As a physical therapy student earning my doctorate level degree I believe that through advancing the educational requirements of the profession, further distinction of physical as a credible medical entity will be upheld and advanced. Strong and significant educational training in human anatomy/physiology and developing a wide understanding of the body and its functions, provides adequate and necessary training to enable only accredited physical therapists to administer comprehensive, knowledgeable, and more importantly scientifically supported patient care.

Therefore, I urge you to consider only permitting licensed physical therapists and physical therapy assistants to administer physical therapy services. I appreciate the time and consideration you, Mark B. McClellan, MD, PhD, have given to my comments.

Sincerely,

Mike Severino

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Dr. McClellan,

Thank you for the opportunity to provide comments on this issue. First, let me state that I strongly support the CMS proposal that individuals providing physical therapy care incident to a physician be required to adhere to the same standards that all other practitioners providing this care are required to meet. I am a physical therapist practitioner in a private practice, and we contract with a hospital for all of their physical therapy services. Having been in practice for 28 years, I am well aware of the expectations of CMS of a physical therapist when we provide physical therapy to a Medicare client. We must be graduates of an accredited program physical therapy program, all of which are now at a post-graduate level, and over 50% of those are at the doctoral level. As licensed medical professionals, we are held to a range of standards by our state practice acts. Additionally, there are extensive standards that we must adhere to as prescribed by CMS, including examination, establishment of a plan of care, and ongoing assessment to maximize the outcome to the Medicare beneficiary.

Given these expectations of physical therapists providing services to Medicare beneficiaries, I do not believe that a physician should be able to delegate physical therapy to someone other than a physical therapist. The Social Security Act requires that in order for a physician to bill 'incident to' for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Given that, I believe the provider should graduate from a physical therapy program and comply with the same standards of care that are required of physical therapists in hospitals and physical therapy private practices.

To delegate physical therapy to an individual without the training and expertise of a physical therapist negates the value of having the standard in the first place. Again, I strongly support your intent, and thank you both for recognizing that a variance in the quality of care will exist if the standards are not equally applied, and for the opportunity to provide you with these comments.

Submitter : Miss. Katherine Bartosik Date & Time: 09/24/2004 12:09:29

Organization : NATA

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 23, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
PO Box 8012  
Baltimore, MD 21244-8012

Re: Therapy-Incident To

Dear Sir/Madam:

I am writing to express my concern over the recent proposal that would limit providers of 'incident-to' services in physician offices and clinics. Consumers deserve a choice to whom is providing their health care. Physicians should be determining which health care provider is better suited to provide rehabilitation for their patients.

Each of these equally qualified medical professionals deserves 'equal footing' in terms of reimbursement for the rehabilitation codes. In today's world of rehab, consumers are exposed to and cared for by certified athletic trainers in physicians offices, rehabilitation companies, and industrial settings. If adopted, this would eliminate the ability of qualified health care professionals to provide these important 'incident-to' services.

Why now, is this proposal questioning the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service? Physicians continue to make decisions in the best interests of the patients. It is IMPERATIVE that Medicare and private payers continue to support physicians in these endeavors and not impose any limitations or restrictions as to who the physician can utilize to provide ANY 'incident-to' service.

CMS is surely receiving comments from Physical Therapists and Physical Therapist Assistants regarding this proposal. The APTA strongly opposes the use of 'UNQUALIFIED PERSONNAL' to provide services described and billed as physical therapy services. These individuals will speak of the 'negative impact' that will be created by allowing unqualified individuals to provide services that are billed as physical therapy services in physician's offices. I could not agree more! Unqualified individuals should not be providing any medical service.

What those individuals will not tell CMS is this:

' All certified or licensed athletic trainers MUST have a bachelor's or master's degree from an accredited college or university.

' Core coursework for an ATC includes:

Human physiology and anatomy

Kinesiology/biomechanics

Nutrition

Acute care of injury and illness

Exercise physiology

Stats and research design

' 70% of all ATCs have a master's degree or higher.

' The services and education of ATCs are comparable to other health care professionals including PTs, OTs, RNs, speech therapists, and many other mid-level health care practitioners.

' A Physical Therapy Assistant has 2-4 years less educational experience compared to an ATC, yet a PTA has a legislative right to be reimbursed for services. Why is this so?

Allowing only PT,OT, speech therapist to provide ?incident-to? outpatient therapy services would improperly provide these groups EXCLUSIVE rights to Medicare reimbursement and DENY the consumer access to quality health care professionals affecting the quality of health care being provided and possibly the costs.

In proposing this change, CMS offers no evidence that there is a problem that is in need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

In summary, it is not necessary or advantageous for CMS to institute the changes proposed. This CMS recommendation is a health care deterrent.

Respectfully,

Katherine E. Bartosik, MEd, ATC  
NovaCare Rehabilitation  
Head Athletic Trainer - Bishop Shanahan High School  
Downingtown, PA 19335

Submitter :

Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

My name is Dennis Spurrier. I am an Athletic Trainer, who has been practicing for 28 years in the Richmond, VA area. My skills as an Athletic Trainer are recognized in the community not only on the "Field", but also in the clinic setting. Many local physicians refer patients to my facility to work with me directly.

I am also an administrator with Healthsouth, and run 3 of their facilities. I have held this position for almost 15 years. I am the Director of Medical Services for the Virginia Special Olympics, director of outreach services in VA for Healthsouth, and coordinator of "on field coverage" for many entities in the greater Richmond area.

On a more humorous note:

Many of the coaches, administrators, parents I have been working with "and on" the last 28 years are now 65+, and expect me to work with them at the clinic. Obviously this does not happen. I feel my skills as an Athletic Trainer, as well as all Athletic Trainers meet, and exceed the needs of all our patients.

I hope consideration will be made to provide the skills and talents of Athletic Trainers for all patients in the clinical setting.

In closing. Athletic Trainers are the only healthcare professionals who provide initial care, first aid, rehabilitation and return athletes to the field.

thank you , Dennis Spurrier

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please do NOT pass this policy whereby a physician can only refer "incident to" services to Physical Therapists. All qualified healthcare providers should be allowed to provide services to patients with a physicians prescription, or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 10-19**

THERAPY ASSISTANTS IN PRIVATE PRACTICE

I support your recommended revision in the level of supervision for the physical therapist assistant in the private practice setting. I work in a hospital setting, and believe that the level of supervision that we are permitted, direct supervision, should also be utilized in private practice. I do not believe that this change will have any negative impact on the quality of care for Medicare beneficiaries.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

PRACTICE EXPENSE

I am proud to be a Registered Physical Therapist for the past 27 years. I have been in private practice, for the past 16 years. I am extremely concerned over the growing number of physician and other health related offices, which are providing so called Physical Therapy services by non qualified personnel. I frequently receive disturbing feedback from patients who have previously received treatment in the above type facilities. It is quite frustrating to hear that patients are continuing to be billed for Physical Therapy services from non registered staff members. I strongly urge you to support and pass CMS-1429-P. Your consideration on this important matter is sincerely appreciated. It is about time that patients receive the professional quality of care that they deserve.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I would like to extend my support for the CMS proposed requirement that physical therapists working in physician's offices be graduates of accredited professional physical therapy program. I also support the need for licensure for these therapists to protect the public and ensure that quality services are provided. My experience on the state licensing board has demonstrated to me many times that only physical therapists or physical therapist assistants working under the supervision of physical therapists are qualified to treat our medicare patients. Unqualified personnel attempting to provide physical therapy often leads to poor outcomes or even injury to patients. Medicare has already set standards for providers in hospitals, physical therapy private practices, CORFs and ORFs, and the same standards for physical therapists providing services should be extended into the "incident to" requirements.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please see attached file



**Department of Health and Human Services  
Centers for Medicare and Medicaid Services (CMS)  
Offices of Strategic Operations and Regulatory Affairs**

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

I was informed of Docket 1429-P recently and I am shocked that anyone would consider giving "incident to" services over to just one group of care providers. There are many other care givers who can help these people. Chiropractors and Massage Therapists are just two examples of other care providers that can provide good and affordable care. It makes me wonder about the kind of care that is being provided when people would take such great pains to "lobby" their way to something when their abilities should be enough to get them there.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-9**

GPCI

We oppose implementation of the proposed GPCI's in localities in multi-locality states with county GAFs exceeding the 5% threshold of their locality and proposed GPCI increases. We propose locality revision as the priority.

Although we support input of state medical associations in locality revision, we oppose the proposal that the state medical association be the only impetus behind locality changes.

Attached are full comments.



September 22, 2004

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: Payment localities

Dear Sirs,

I am writing on behalf of the Santa Barbara County Medical Society in response to proposed rules regarding the current Medicare physician payment localities (69FR47504) and GPCI's. We have extensively studied Medicare physician payment localities and have concluded that the current locality structure needs revision. I would like to comment on your proposed rules in regards to physician payment localities and the proposed GPCI's.

In 1997, under the authority given the Secretary to set payment area localities by Section 1842 of the Social Security Act, HCFA implemented Option 1i 5-percent threshold with restructuring of subcounty payment areas to reduce the number of physician fee schedule payment localities from 210 to 89 (61FR59497) and ruled the county as the basic locality unit to provide a national uniform physician fee schedule structure (61FR59494). A 5 percent threshold was applied to existing localities created nearly forty years ago at the inception of the Medicare payment system to create the new payment localities, exceptions were made in Massachusetts, Pennsylvania and Missouri to accommodate high cost areas. In the ruling, there was no provision for future locality revision and there has been no published ruling regarding revising multiple locality states not wishing to form statewide localities. In response to comments regarding managing future cost changes, it was stated "while we do not plan to routinely revise payment areas as we implement new GPICs, we will review the areas in multiple locality States if the newer GPCI data indicates dramatic relative cost changes among areas." (61FR59497). It was also stated "our proposal is based strictly on the application of statistical methodology comparing area costs. Arbitrarily taking away money from a high cost area merely to redistribute it to other areas would violate our criteria and underpay the high cost area while overpaying the low cost areas." (61FR59496).

Many counties in multi-locality states currently have a GAF's that exceed their locality GAF by the 5 percent threshold used in forming localities in 1996. (County-wide data provided by R. Ensor-for specifics refer to those files). Inconsistencies in the current locality structure are due to changing demographics that have occurred since original localities were developed. As a result, some counties receive payments well below the 5% threshold of their county's cost indices. Border differences between high cost counties approach twenty five percent in some instances. We consider these dramatic relative cost changes that warrant locality revisions. Under the rules established in 1997 and with the authority given to the Secretary, those counties should be restructured into localities that more accurately reflect the County's costs. These revisions would occur within the existing rulemaking process. We support your proposal to examine alternatives for reconfiguring the current locality structure and encourage an action now with the implementation of your proposed GPCI's.

Several multi-locality states have proposed GPCI increases for 2005 and 2006 in localities containing high cost counties exceeding the 5% threshold primarily due to the increased indices of those same high cost disadvantaged counties rather than each of the component counties. For example, California Locality 99 has several high cost counties exceeding the 5% threshold with significant increases in their county's GAF accounting for the proposed increase in Locality GAF for 2005 and 2006 while the remaining lower cost counties have little change in their GAF's. Rather than apply the increase to the entire Locality, I propose that CMS remove the highest cost counties sequentially so that there is no increase or decrease in the proposed GPCI's in the remaining locality for 2005 and 2006 when compared with 2004. In California Locality 99, for example, such an action would create new payment localities for Santa Cruz and Sonoma Counties in 2005 and Monterey County in 2006.

Due to the wide geographic cost differences that have developed in this locality, we anticipate and encourage future locality revision. Applying the GPCI increase of those high cost counties to the Locality weighted average without revision magnifies the disparity within the Locality. Implementing the proposed increases simply leads to greater reductions to remaining counties when reconfiguration occurs.

In California Locality 3, Marin County has a GAF exceeding the 5% threshold. Removing Marin County instead of implementing the proposed GPCI increase would result in a fraction of a percentage decrease in the remaining counties' GAF. Implementing the GPCI as proposed would automatically create a 5% negative impact to remaining counties if future revision occurs. The same process could be applied to other multi-locality states with proposed GPCI increases and high cost counties exceeding the 5% threshold such as Washington State (Snohomish Co.), New Jersey, and Maryland. Such a measure would be a first step in Locality revision. It avoids the negative impact of the proposed GPCI's that would occur with future locality revision while at the same time avoids payment reductions to the remaining locality with current locality changes. Implementing the GPCI's and not revising localities compounds the current problem, making future locality changes more difficult.

One year ago, we proposed revision of California Locality 99 that would have included the highest cost four counties exceeding the 5% threshold and resulted in an estimated 1.2% Locality 99 GAF reduction. The same four counties removed with the proposed GPCI's will result in a 2.2% reduction. Delaying revision in localities with historic increases in cost indices such as California makes bigger "losers" of remaining counties when those revisions ultimately take place.

If it is not possible to make locality changes as proposed with the updated GPCI's, we would suggest that the updates not be implemented in localities of those states such as ours considering locality revision. In a state as large as California, a sixty-day comment period is insufficient time for an organization such as the California Medical Association to respond in a cohesive manner to such a major proposal. A delay in at least two of the problem localities, if proposed by the CMA, would allow additional time for a locality proposal without additional negative impact of the implemented GPCI's as discussed above. We would support such a delay, if the California Medical Association indicated to you that a proposal was imminent.

In your consideration for alternatives to locality revision, we request the established 5 percent rule be re-applied to existing localities in multi-locality states nationwide using the County as the basic unit. Of all the options we have considered, this would have the least negative impact on remaining Locality counties. A variation of this proposal would be to fundamentally

restructure localities based on county costs as represented by GAFs with some geographic consideration as was done in exceptions to the 5 percent rule in Massachusetts, Pennsylvania, and Missouri in 1996 (61FR34620). As stated, such revision would result in redistribution of money resulting in lower payments to remaining counties. As in 1997, those lower payments could be implemented over a two year period and in some instances would be offset by SGR updates. A threshold could be pre-determined (such as the amount of the scheduled SGR in years of increase) as an offset to limit the negative impact or avoid payment reductions. In larger negative impact situations, legislation setting payment floors for localities and applying adjustments to unaffected localities would be necessary. We are considering such an action with the California Medical Association. States should also be given the option to maintain the existing locality structure, if all counties agree.

Although we agree that state medical associations should be an impetus behind locality changes, we disagree with your proposal that state medical associations should be the impetus behind locality changes in multi-locality states. State medical associations have the responsibility to represent all counties and, in a system that creates both winners and losers, can be so conflicted that an objective resolution cannot be obtained or the resolution is so compromised to achieve consensus that it becomes ineffective. A single county in state could be significantly disadvantaged but unable to propose change because of a majority of counties, benefiting from that single county's underpayments, would overrule. Congress delegated CMS to administer payment localities because of their expertise and objectivity, not state medical associations, and it is CMS's responsibility to develop objective criteria and thresholds for locality formation and revision or refer to an impartial expert third party that is capable of resolving conflicts.

In summary, the current locality structure in many multi-locality states does not fulfill the 1996 objective of minimizing input price difference and county boundary difference and warrants revision. Implementing the proposed GPCI's and further delaying locality revision in some states will worsen the negative impact of that revision. Future locality revision should occur with introduction of new GPICs to minimize input price differences within localities. Methodology should be developed to automatically accommodate locality revision with new GPICs or define limits of existing localities that would prompt revision rather than requiring a proposal from state medical associations. A process for locality review and appeal should be developed that does not require a resolution from state medical associations.

The intent of the GPCI is to reimburse physicians appropriately for geographical differences in the cost of providing medical care. The intent of establishing localities was to simplify but not undermine GPCI reimbursement. In multiple locality states such as California, maintaining localities with large differences among the basic locality units (defined by the rulemaking process as greater than 5 percent) violates criteria established in 1996, undermines the intent of GPCI, and, therefore, warrants revision of those localities.

Sincerely,



Edward S. Bentley, M.D.  
President  
Santa Barbara County Medical Society

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 20-29**

THERAPY - INCIDENT TO

Please do NOT pass this policy whereby a physician can only refer "incident to" services to physical therapists. All qualified health care professionals should be allowed to provide services to patients with a physicians prescription or under their supervision. Please keep in mind the positive effects that alternative therapies have on stress reduction and disease control. Certified Massage Therapists should be included. Thank you.